entities involved in establishing Federal advisory committees to appropriately consider member status issues when creating these committees. The template is still in a draft form and OGE will continue to work with GSA on preparing the final template.

3. GSA FACA Training Support

See comment 10.

The proposed report states that changes should be made to the training materials used at GSA's FACA Management Training Course to address concerns about the overall adequacy of OGE guidance on the SGE/representative designation issue. The course provides 20 pages of written materials on ethics, including five pages devoted to issues involving the status of members serving on these committees. For the reasons noted above, we believe the suggested changes to the text arise from an unreasonable interpretation of OGE guidance. Much of the guidance for distinguishing between SGE's and representatives comes from a Presidential memorandum that was issued shortly after enactment of the legislation creating the SGE category. Because much of the course material dealing with the SGE/representative distinction comes from that memorandum, we would not support any changes that would be inconsistent with the weight of that contemporaneous interpretation of the SGE category.

Nevertheless, OGE will continue to work with GSA to modify these materials to make clearer for attendees the SGE/representative distinction. In addition, OGE instructors at the course will continue to ensure that the content of these course materials dealing with this issue are fully discussed with course attendees.

4. OGE Ethics Conferences

See comment 11.

Almost every year since 1996, OGE has presented a session on FACA issues at its annual ethics conference. For example, a session at the 2003 conference was principally devoted to "designation" issues involving Federal advisory committees. The session discussed recent reviews conducted by both OGE and GAO involving the management of Federal advisory committees at several agencies and some of the issues raised by those reviews. In particular, during the conference panel session, the Department of Veterans Affairs (VA) Committee Management Officer discussed his agency's process for designating advisory committee members within the VA.

5. Additional SGE Guidance and Training Materials

See comment 12.

Since publishing OGE informal advisory opinion 82 x 22, OGE has issued other advisory opinions that have discussed SGE and/or representative status (e.g., 87 x 12, 88 x 16, 90 x 5, 90 x 22, 92 x 25, 93 x 14, 93 x 30 & 95 x 8). Most recently, in February 2000 OGE issued a summary regarding "Conflict of Interest and the Special Government Employee," which was subsequently issued as OGE Informal Advisory Opinion 00 x 01. A substantial portion of this summary is dedicated to explaining the concept of what is an SGE, and distinguishing SGE's from non-employees such as representatives and independent contractors. Ethics officials were asked to disseminate the summary to other components within their organizations (such as regional offices) who they thought might encounter questions pertaining to SGEs.

6. Continuing Review

See comment 13.

Finally, many of the issues regarding SGE/representative designations can be better addressed when Federal advisory committees are being created. In this regard, OGE monitors and comments on proposals to create advisory committees to ensure that SGE/Representative designation issues are fully considered.

Conclusion

Thank you again for the opportunity to comment on the proposed report. As noted above, OGE recognizes the importance of correctly applying the criteria for distinguishing between advisory committee members who are serving as SGEs and members who are serving as representatives, and has devoted considerable attention to this issue. We therefore welcome your contribution to our continued efforts in this area.

If you need any further assistance regarding any particular item discussed in this letter, please contact OGE Associate General Counsel Vincent Salamone or OGE Associate General Counsel Richard Thomas. Their telephone number is 202-482-9300.

Sincerely,

Marilyn L. Glynn
Acting Director

The following are GAO's comments on the Office of Government Ethics letter dated March 17, 2004.

GAO Comments

1. We continue to believe that OGE's ongoing efforts to encourage agencies to evaluate whether appointments should be made as special government employees or representatives would prove more effective if clear, unambiguous guidance addressing the limitations we identified were available to agency staff.

   The draft and final reports present the OGE guidance as a factor in some agencies' inappropriately appointing some members as representatives and acknowledge OGE's concern that some agencies may be doing so to avoid the conflict-of-interest reviews. Unless OGE clarifies the limitations in the guidance identified in our report, we believe progress in moving agencies toward appropriate appointments will likely continue to be slow or nonexistent—remembering that the 1982 guidance was issued because of confusion over the proper use of representative appointments. Unambiguous guidance would help all agencies implement it; would support more effective oversight by ethics officials, including OGE, and by Inspectors General; and would make it more difficult for any agency to misapply the guidance and misidentify certain advisory committee members as "representatives."

2. The clarifications we identified do not change the criteria but rather amplify them to address areas where continued confusion or misuse has occurred. The 1982 guidance was developed to address uncertainties regarding when agencies should appoint individuals as either special government employees or representatives. In our view, the findings in our report indicate that additional clarifications are warranted. Along these lines, we note that when OGE's staff determined in 2002 that some agencies use only representative appointments, they suggested that additional training materials may be appropriate. The staff suggested a communication to agency ethics officials to assist them in making the determination for their committee members. Our draft and final reports recommend revisions to the guidance and the training materials.

3. Given that agencies are appointing representatives to represent their individual fields of expertise and that OGE agrees this use of representative appointments is not appropriate, we believe OGE should revise its guidance to clarify that such appointments generally are not

appropriate. (We note that an exception would be if a committee were considering an issue that would impact a particular group, for example, physicists or biologists—a case in which a group of experts would be stakeholders in the matter being considered.) Instead, OGE's response is to state that it is not logical to say that a field or area of expertise is a "group of persons" and to disagree that clarification to its guidance may be warranted to eliminate this practice. It is possible, as OGE suggests, that some agencies understand the guidance and are simply disregarding it. However, we believe ambiguities in the OGE guidance may provide agencies with some "cover" to support their interpretations. In such cases, clear guidance would make it more difficult for them to continue to misapply it. In addition, we direct OGE's attention to the responses to this report from Interior, NASA, and Energy (see apps. XV, XVI, and XVII), which suggest that clarifications to the guidance regarding the appointment of representatives to represent fields of expertise may be necessary.

4. On the basis of our work at several agencies and our review of the OGE guidance, we continue to believe some clarification is needed vis-à-vis the use of the term "represent" and its cognate forms. As the draft and final reports state, OGE's direction to agencies in making decisions regarding representative appointments is to use "words to characterize them as the representatives of individuals or entities outside the government who have an interest in the subject matter assigned to the committee." Notably missing from OGE's specific direction to agencies is a focus on the nature of the advice they will be giving—that is, that they are to represent stakeholder views. This is in contrast to OGE's direction to agencies regarding special government employees that does focus on the fact that they are to exercise individual and independent judgment. Although OGE's guidance does provide helpful examples to agencies in examining statutory language to determine whether committee members are actually intended to serve as representatives of interest groups, we believe that language in the conclusions section of the guidance that directs agencies how to indicate the type of appointment contradicts the examples that OGE cites. We have clarified the final report to indicate that we were specifically discussing the conclusions section of the OGE guidance. We also note that OGE developed these conclusions in 1982—that is, it is not citing the 1962 guidance the agency is hesitant to revise. Overall, we believe that clarifications, but not departures from the criteria regarding appointments, are needed.

We point OGE also to the comments from the Interior (see app. XV) on the matter of the term representative. Interior stated that "GAO agrees that the statute authorizing the National Cooperative Geologic Mapping Advisory Committee' calls for the committee to include…representatives,' but then goes on to say that the statute does not "clearly and unambiguously call for these members to be appointed as representatives rather than special government employees.'." Interior then characterized our statements as a contradiction and said that the Secretary of the Interior "reasonably may interpret such a statute by relying on its plain language….". In our draft and final reports, we indicate that it is not clear what point of view the private sector and academia members could be called upon to provide if appointed as representatives, and the statute did not appear to clearly mandate that they be appointed as representatives—that is, it may be using the term generically. We continue to believe that the statute does not clearly and unambiguously call for representative appointments and that this example underscores the need for OGE clarification as we recommend.

5. Seeking recommendations for advisory committee members from outside groups or organizations does not tend to support either representative or special government employee status. As noted in the draft and final reports, obtaining outside nominations is a common practice for committees appointing special government employees; thus, it is not used only for representative appointments. We think it would be appropriate for the OGE guidance to reflect current practices regarding nominations to federal advisory committees and avoid the potential of agencies' giving undue weight to this criterion.

6. We are only recommending clarifications to OGE's guidance, not changes to the fundamental principles or criteria upon which OGE based its guidance. See also comment 2 above.

7. Our draft and final reports highlight the various efforts OGE discusses below. However, we believe the effectiveness of these efforts will continue to be reduced until OGE's guidance on appointments is clarified.

8. OGE has subsequently clarified this comment. The program review cited in the comment led to a recommendation that an agency reassess the status of employees serving on a federally chartered corporation and not on a federal advisory committee.

9. We have not evaluated the template that was still in draft form during our review.

10. OGE does not explain its view that the clarifications to the GSA FACA management training course that we identified in the report represent an unreasonable interpretation of OGE guidance. We continue to believe the suggestions our draft and final reports highlight would improve the effectiveness of the training sessions. For example, the GSA materials state that representatives *may* (emphasis added) represent the views of a particular industry or group. It is not clear to us why OGE would object to revising the FACA training materials to be consistent with OGE's guidance that representatives *are* expected to "represent a particular bias."

11. The draft and final reports identify the session at the 2003 OGE Ethics Conference cited in OGE's letter.

12. The draft and final reports cite the most significant and comprehensive OGE guidance documents addressing representative appointments, including OGE Informal Advisory Opinion 00 x 01 highlighted by OGE in its comments. (In the report text, we refer to this guidance as OGE's February 2000 guidance, and we have added a legal citation to it in a footnote.) We note that this opinion includes one paragraph addressing representative appointments and states that representatives are described more fully in OGE Informal Advisory Letter 82 x 22, the guidance document cited in our draft and final reports as OGE's principal guidance on the issue of appointment categories for federal advisory committees.

13. We support OGE's commitment to monitor and comment on appointments to newly created committees. However, in light of evidence that some appointments to existing committees are inappropriate, we believe it is appropriate to also review the appointments for approximately 950 advisory committees that are currently active.

Comments from the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

MAR 19 2004

Ms. Robin M. Nazzaro
Director
Natural Resources and Environment
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Nazarro:

Enclosed are the Department's comments on your draft report entitled, "Federal Advisory Committees – Additional Guidance Could Help Agencies Better Ensure Independence and Balance." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Dara Corrigan
Acting Principal Deputy Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

COMMENTS ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GENERAL ACCOUNTING OFFICE'S DRAFT REPORT, "FEDERAL ADVISORY COMMITTEES: ADDITIONAL GUIDANCE COULD HELP AGENCIES BETTER ENSURE INDEPENDENCE AND BALANCE" (GAO-04-328)

The Department of Health and Human Services (HHS) appreciates the opportunity to comment on the GAO's draft report. The Department strives to abide by the General Services Administration's (GSA) guidelines and the General Administration Manual that describes the Department's advisory committee policies.

This report will be useful in evaluating current practices for appointing members to serve on Federal advisory committees. In addition, GAO has provided a number of interesting ideas for determining balance in points of view and ensuring transparency in the advisory committee process.

Although we agree in principle that the information the Environmental Protection Agency (EPA) collects on their potential nominees may be useful in the selection process, we also believe that a few of the practices identified may have unintended consequences. We are concerned about the collection of background information on prospective members to understand their points of view.

See comment 1.

We believe both the scientific community and the public at large is more comfortable with a process that seeks to achieve balance through a mix of expertise, background, and personal experience, rather than through a process based on seeking out some indefinable range of personal opinion. In many cases, points of view can be misinterpreted based on the frame of reference of the individual reviewing the nominee, either the public, Federal staff, or both. Also, we feel that this type of activity may make Federal agencies more vulnerable to litigation if potential nominees think that they were not selected because of their points of view rather than their expertise. We think this practice might not be acceptable to our nation's scientific community.

See comment 1.

We feel that it is more appropriate to base the selection of members on the scientific expertise needed for each committee. For instance, the National Institutes of Health (NIH) has a vast number of scientific and technical advisory committees. NIH first seeks balance in the area of scientific expertise but also considers several other factors: geographic, ethnic, gender, minority status, bias, and orderly rotation, that helps to ensure that committees are balanced in terms of points of view. For example, when NIH seeks to recruit scientists to serve on a committee looking at human genetics issues, they try to recruit a diverse group of individuals with varied backgrounds to bring balance to this committee. Therefore, NIH might look for experts with specialties in human genetics, ethics, law, psychology, molecular biology, public health, social sciences, bio-terrorism, forensics, healthcare, and other relevant fields. We believe that such diversity in the selection process would invariably ensure diverse points of view and balance.

HHS agrees with GAO's recommendation that advisory committee operations and member appointments should be a transparent process. We believe in the public notification process and feel that the public should be privy to advisory committee activities. We also agree that it is in the best interest of both the public and the Government to disclose information about the

See comment 2.

formation and operation of advisory committees. Although the public notice process to obtain comments on proposed candidates might be feasible for some HHS committees, it would not be workable for all of them. Unlike EPA with 24 committees, HHS had 234 active committees in 2003 and various subcommittee structures within these committees. Some HHS agencies are limited by legislation in terms of the appointment process. For example, most of NIH's national advisory councils are established under Section 406 [284a] (c) of the Public Health Service Act. This law requires that the Secretary, HHS, fill all national advisory council vacancies within 90 days from the date the vacancy occurs. Soliciting public input could gravely delay each committee's ability to meet the requirements of this law, accomplish its charge and appoint its members. It could also seriously increase administrative costs for staff and contract support to handle this function.

See comment 3.

The Federal Advisory Committee Act (FACA) requires that membership be "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." This is reflected in the Food and Drug Administration's (FDA) advisory committee regulations (see 21 CFR 14.40(f)(2)). The FDA has 31 of the HHS advisory committees, all highly technical. The draft report also states that, for science and technical committees, viewpoint balance is appropriately achieved by obtaining a variety of scientific expertise and perspectives. FDA agrees and its advisory committee regulations have adopted this approach. For technical committees, the agency must ensure that prospective members have expertise in the subject matter with which the committee is concerned and that they have diverse professional education, training, and experience (see 21 CFR 14.80(b)(1)(i)). However, the draft report implies that agencies should also screen for policy views, as a way to ensure impartiality. FDA does not screen for policy views on technical committees; rather, its approach follows the National Academy of Sciences' recommendation that appointments to scientific advisory committees be based solely on a person's scientific or clinical expertise or his or her commitment to and involvement in issues of relevance to the agency's mission. While FDA does not screen for policy views on technical committees, prospective members are subject to conflict of interest restrictions, as established by Congress, and the agency may remove a member who demonstrates a bias that interferes with the ability to render objective advice (see 21 CFR 14.80(f)).

See comment 4.

GAO's draft report cites EPA as the benchmark to which all other agencies should aspire. A previous GAO report criticized the advisory committee practices of EPA. It was the FDA that assisted in the remediation of the EPA advisory committees. The draft report does not recognize this effort on the part of FDA.

See comment 5.

In the interest of transparency, GAO's draft report states that agencies could make more information available on the operations of advisory committees. FDA's selection process is clearly spelled out in its regulation as well as in every Federal Register notice calling for nominations. On a product specific meeting, a disclosure form with a scope and type of conflict is disclosed and signed by the member. For a general matters meeting, it is disclosed that waivers are granted and the impact will be minimized by the fact that large segments of industry will be impacted in the same way. FDA regulations also state that if the discussion turns specific, either additional waivers will be issued or the meeting will cease. FDA may be the only

agency that posts, on the web, a Conflict of Interest algorithmic document that demonstrates exactly how the agency makes decisions relative to the scope and magnitude of a conflict.

FDA stands behind its work to ensure that the advisory committees are balanced, not only demographically, but by scientific point-of-view. In addition, FDA makes every effort to ensure that all its committees have its stakeholders represented i.e., academics, industry, patient advocates and consumer advocacy groups. FDA is secure in the knowledge that it makes every effort to have an open process of member recruitment, of conflict of interest matters and of balance to achieve the recruitment of the best scientists to provide the most cutting edge scientific advice for its regulatory process.

It is departmental policy to avoid excessively long individual service on advisory committees. The 2002 roster for Childhood Lead Prevention and Poisoning Advisory Committee included twelve individuals serving expired terms, some of them serving on terms overdue since 1998. As noted in the report, the Office of the White House Liaison has enforced that all advisory committee members serve no longer than 180 days beyond the expiration of their terms to ensure a proper turnover of committee members, which the Department believes contributes to maintaining independent and balanced advisory committees.

Again, we appreciate the opportunity to be a part of this review and find the report's recommendations of great value. HHS advisory committees play an integral role in developing health and science policy for the nation and the world and determining the scientific merit of future research. We will continue to review and evaluate each of the ideas presented in the report to identify those that may be implemented for our advisory committees. In addition, since the NIH has 145 of the HHS advisory committees, they have volunteered to work with GSA to assist them in implementing the 12 recommendations noted in the report.

The following are GAO's comments on the Department of Health and Human Services's letter dated March 19, 2004.

GAO Comments

1. The draft and final reports identify processes that include an evaluation of potential members' points of view *relevant to the subject matters advisory committees will consider* while focusing on the relevant expertise needed. Thus, it is not accurate to characterize the report as espousing "a process based on seeking out some indefinable range of personal opinion." The examples in the report of agency processes include targeted evaluations of points of view that ask potential members if they have made public statements or taken positions on the issue or matters the committee will consider, including expert legal testimony on the issue or matters. The processes cited also ask the potential members to identify and describe any reason they may be unable to provide impartial advice *on matters before the committee* and any reason their impartiality *in the identified matter* might be questioned. We have added the phrase "regarding the subject matters being considered" in several other places in the final report in which we discuss determining the viewpoints of potential members for further clarity on this point. The report also points out that if agencies use a systematic, consistent, and transparent approach to obtaining relevant information from prospective committee members, it is unlikely they would approve questions that are generally inappropriate in a professional working environment, such as questions about party affiliations or political viewpoints that some committee members have reported being asked. In our view, agencies that do not proactively and transparently address the relevant points of view of prospective committee members regarding the matters the committees will consider are more likely to be subject to questions about committee balance from the public and users of the committees' products than those agencies that use such processes. That is, even if agencies choose to either not identify or acknowledge relevant public positions its committee members have taken on matters the committees will consider, others are often aware of such positions and are likely to raise questions about them. Such circumstances can have a negative impact on the credibility of the specific committees involved and on federal advisory committees overall. We believe this practice has been the case regarding some HHS federal advisory committees about which scientists and others have expressed concerns. Finally, in terms of HHS's concern that obtaining information on relevant points of view might not be acceptable to the nation's scientific community, our report

shows that both the National Academies and EPA routinely obtain such relevant information from its prospective members.

2. The report identifies the practice of soliciting public input on nominations to advisory committees, used by the National Academies and some federal advisory committees, as one that can be helpful in ensuring an appropriate balance of points of view of committees, particularly those that address sensitive and controversial matters. Agencies can determine whether to use this tool on a case-by-case basis. Thus, we do not disagree with HHS's comment that obtaining comments on proposed candidates might be feasible for some HHS committees but not workable for all of them.

3. Although we agree with HHS that FDA should emphasize technical qualifications when selecting advisory committee members, we also believe that it is important for agencies to assess prospective members for viewpoints that they have that are relevant to the work of the committee (see also comment 1). HHS says that FDA follows the National Academy of Sciences' recommendation that the appointment of members to scientific advisory committees be based primarily on expertise and involvement in relevant issues. This report notes that the academies also seek to determine, through a few simple questions, whether there is any reason to believe that the impartiality of members or prospective members might be questioned.

4. EPA made changes in how it manages the Science Advisory Board in response to the specific recommendations in our 2001 report.[1] We did not attempt to determine any role FDA may have had in assisting EPA, but we note that EPA, unlike FDA, revised its processes for achieving overall balance in terms of points of view, expressly integrating it with its reviews for potential conflicts of interest and obtaining relevant information prior to the appointment of committee members.

5. We agree that FDA provides useful information about its selection process, but we continue to believe that FDA and the other agencies could improve their processes for balancing committees. The draft and final reports highlight FDA policies for public notice of waivers. We note that the selection and waiver processes used by FDA are not used by HHS, CDC, and NIH.

[1]GAO-01-536.

Comments from the Department of the Interior

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

United States Department of the Interior
OFFICE OF THE ASSISTANT SECRETARY
POLICY, MANAGEMENT AND BUDGET
Washington, DC 20240

TAKE PRIDE IN AMERICA

MAR 1 8 2004

Christine Fishkin
Assistant Director
Natural Resources and Environment
United States General Accounting Office
Washington, D.C. 20548

Re: DOI Comments on GAO Draft Report on Advisory Committees

Dear Ms. Fishkin:

Thank you for the opportunity to review the GAO's draft report entitled, "Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance."

We agree with much in the report; it contains many useful recommendations that can be used to enhance the successful use of advisory committees. However, the Department has a number of general and specific concerns with the GAO analysis.

Enclosed please find DOI's response. If you have any additional questions, please feel free to contact us.

Sincerely,

P. Lynn Scarlett

Department of the Interior Comments on GAO Draft Report on Advisory Committees

Following are the Department's response to the GAO's draft report entitled, "Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance."

See comment 1.

We agree with much in the report; it contains many useful recommendations that can be used to enhance the successful use of advisory committees. However, we note that the GAO's focus on scientific advisory committees ignored the wide ranging purposes and programs for which advisory committees are used in many agencies, such as managing public lands and natural resources. As a result, many of the report's recommendations and observations about independence and balance of committees, while useful, have limited applicability in non-science settings. GAO should clearly identify the purpose and scope of this report as focusing on science committees.

See comment 2.

The Department strongly disagrees with GAO's basic approach to the concept of balance that is required under the Federal Advisory Committee Act (FACA). The GAO's approach reflects neither actual experience nor practical considerations associated with creating, staffing, and managing advisory committees under the FACA. On page one, and throughout the report, GAO repeats the basic point that "Specifically, individual committee members providing advice to the government must be free from significant conflicts of interest – that is, they must be independent." It is not clear exactly where the report's apparent requirement that *individual* committee members be "independent" originates. In Section 5 of the FACA, Congressional committees are directed to "...assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or any special interest, but will instead be the result of the advisory committee's independent judgment." Though this statutory requirement, by its terms, is not applicable to discretionary committees established by agency heads, it is repeated verbatim in the GSA regulations at 41 C.F.R. § 102-3.105(g), as a responsibility of agency heads for committees they establish. An "independent" committee member is simply never discussed.

See comment 2.

The report's focus on "independence" of individual committee members has several practical and conceptual difficulties. First, it does not accurately reflect the FACA's and the regulations' requirement that the *advisory committee* itself remain free from inappropriate influence and that its recommendations result from its independent judgment. There is no guarantee that a committee made of "independent" members will also be a committee that is not inappropriately influenced by the appointing authority, or that the committee is acting on its independent judgment. The more logical way to implement these provisions would focus on the operation of the committee itself, ensuring that the appointing authority does not mandate any particular results from the committee members and that the committee is not structured in such a way as to give any special interest control over its advice. For example, although consensus is often desired on advisory committees, mandating a unanimous vote in support of committee advice would enable a single member to thwart other members of the committee by refusing to support the other member's preferred advice. This would not only be inappropriate influence, but it would also prevent the committee from giving its independent judgment, as it would make the

committee potentially beholden to a single member.

See comment 2.

The report unnecessarily focuses on a requirement for membership that does not exist, i.e., "independence." The report therefore detracts from addressing the membership requirement that does exist: that the committee be fairly balanced in its membership in the points of view to be represented and the functions to be performed. Once again, this requirement only goes to the balance of the committee as a whole, though the balance may only be addressed by reference to the "points of view" of individual committee members, i.e., there is balance on a committee when a member with a particular "point of view" is on a committee with others with differing or conflicting points of view. The relevant question is how to determine what "point of view" to attribute to a member and how to distinguish one point of view from another, to reasonably assure balance on the committee as a whole. Using "independence" as a criteria for membership at best does not help this analysis, and at worst it confuses the issue and hinders an agency in seeking the requisite balance on its committees.

See comment 2.

The report defines "independence" as freedom from "significant conflicts of interest," a definition that appears to conflate the ethics requirements applicable to Federal employees (including SGEs) and some concern over complaints about certain advisory committee members into an entirely new, inappropriate, and unworkable standard. There is nowhere in the ethics rules that states that even full-time Federal employees must be free from "conflicts of interest," let alone "significant conflicts of interest." The system instead is set up to identify the financial interests that may lead to conflict (primarily via financial disclosure reports), and then instructs employees: 1) to avoid participating personally and substantially in particular matters that may directly and predictably affect their financial interests (18 U.S.C. § 208); and 2) to avoid "participating" in a particular matter involving specific parties in circumstances where a reasonable person may question their impartiality (5 C.F.R. § 2635.502). In each case, the agency may nonetheless authorize participation. Further, " substantial" conflicts (those materially impairing the employee's performance of official duties or requiring disqualification too often) are dealt with by divesting the interest. See 5 C.F.R. § 2635.403(b). The report attempts to short-circuit this system by imposing the vague "independence" standard on advisory committee members, as some sort of appointment requirement.

See comment 3.

The report's emphasis on the "independent" committee member standard ignores the agencies' ability to work with committee members to ensure that they do not violate the ethics rules. As set forth in the system described above, the question of whether or not a member should participate in a particular committee function is properly resolved on a case-by-case basis, evaluating the nature of the committee action and the nature of the financial interest involved. For example, it is not clear when casting one vote out of a number of committee member votes that results in a committee's advice to a Federal agency will be "personally and substantially" participating in a matter sufficient to trigger the conflict of interest statute. The question of whether a particular piece of advice will "directly and predictably" affect a financial interest also should be closely considered. Should an actual conflict exist, the agency should be able to determine whether to authorize participation, as it could with other matters in which employees are involved. Accordingly, the report should focus more on how an agency may effectively address ethics-related issues in terms of participation of members in committee activities and in terms of how to articulate, achieve, and publicly support the fair balance of its committees.

See comments 3 and 4.

See comment 2.

Imposing "independence" as an appointment requirement does not help an agency bring the requisite balance to a committee. It will necessarily be very difficult, and ultimately not worthwhile, to attempt to determine whether a committee member or the committee member's "point of view" is "independent," whatever that means. The report recommends that agencies identify and systematically collect and evaluate information pertinent to determining "points of view" of committee members. Scientific advisory committee members are generally chosen for their expertise and objective understanding of the science involved and not on the basis of perceived "points of view." This is not really the relevant question. The relevant question is

See comment 5.

whether a committee has balance in terms of the points of view to be represented and the functions to be performed. The report would be more useful if it would focus on suggestions regarding how to help agencies define and achieve such balance in points of view when exercising their discretion in committee appointments.

See comment 6.

Departmental officials have informed your staff of the many steps we have taken over the past 18 months to improve the way we identify and appoint advisory committee members as special government employees. I understand that this information was shared with you at one of your initial meetings at the Department in June of 2003. The draft report repeatedly states, however, that this information was provided only in January of this year. It is important that GAO properly acknowledge the efforts the Department is undertaking in this area.

Our other specific comments are set forth below.

See comment 7.

P. 4: Last sentence: It is inaccurate to single out three agencies to say they "do not conduct conflict-of-interest reviews for members appointed as representatives." First, it is unlikely that *any* agency does this for representatives, not just these three. Second, given the differing levels of ethics screening that may be done (such as for BLM Resource Advisory Councils), the more accurate statement is that agencies do not collect and review OGE Form 450s (or other approved form) for representatives. We recommend that this substitution be made throughout the report or else define "conflict-of-interest reviews" as a term of art meaning use of the OGE Form 450 or similar form.

See comment 8.

P. 8: Last paragraph, second sentence: GAO ignores the authority of agency heads to exercise discretion under their organic statutes to create advisory committees that are not expressly authorized by Congress or by a president.

See comment 9.

P. 16: The definitions on this page and on page 17 should be clarified as early as possible in the report to ensure that readers understand the two categories of membership (representatives and special government employees).

See comment 10.

P. 20: Last paragraph: GAO significantly misconstrues DOI's "agency culture," not only on this page but throughout the draft report. With the majority of its committees advising the Secretary on the management of public lands, DOI historically has strongly believed that its committees members should represent local stakeholders. Thus the practice of appointing representatives is based on decisions strongly rooted in DOI's authorities, responsibilities and philosophies. Ignoring the appropriate use of representatives, GAO

repeatedly assumes without factual support that most representatives should have been appointed as SGEs.

See comment 11.

P. 21: GAO's generalization that representation of fields of expertise is not appropriate ignores the importance of such representation to some committees. However, we agree that agencies have proper guidance in how and when to use such expertise.

See comment 12.

P. 24: First paragraph: Reference to DOI's efforts to add ethics language to all FACA charters misleadingly suggests that DOI began this effort in January 2004. GAO is aware that DOI began this effort in 2003 in response to OGE's 2002 study.

See comment 13.

P. 25: First paragraph: In paraphrasing DOI officials regarding the tendency "to err on the side of continuing with representative appointments," GAO omitted important information that was presented in the same discussion. That is, where the purpose of the committee is to advise the Secretary on the management of public lands or other resources, the Department firmly believes the views of local stakeholders are essential to sound and useful advice. In such cases, DOI is likely to continue to appoint representatives. In doing so, it does not "err," especially if an authorizing statute does not restrict the Secretary's discretion to do so. Rather, GAO errs by invoking OGE's guidance without regard to the stated purpose of the advisory committee.

See comment 14.

Second paragraph: GAO agrees that the statute authorizing the National Cooperative Geologic Mapping Advisory Committee "calls for the committee to include ... representatives," but then goes on to say the statute does not "clearly and unambiguously call for these members to be appointed as representatives rather than special government employees." Notwithstanding this apparent contradiction, the Secretary reasonably may interpret such a statute by relying on its plain language, especially where the Secretary desires representative advice to assist a committee's function.

See comment 15.

P. 27 - 35: The report continually confuses the distinctly separate concerns for balance and avoiding financial conflicts of interest. Additionally, GAO's positions regarding a committee's balance and perceived objectivity when compared to points of view of its members are simply unrealistic and impractical, and unrelated to the actual functioning of advisory committees. The kinds of inquiries into the biases and points of view of potential appointees recommended by GAO is intrusive, of little practical utility, and will turn qualified individuals away from government service. GAO apparently has a single concept of how to achieve balance and seems to ignore the FACA's requirement that committees be balanced based on the function they are called upon to perform. Further, representatives are placed on committees precisely because of their stated representative interests; because they are not subject to the ethics rules, it is illogical to assert that their participation is improper on the basis of bias. GAO's view that agencies cannot properly balance their committees without understanding all perceived biases of all members is simply fallacious. Finally, as the report notes on p. 37, courts have interpreted the FACA as giving agencies broad discretion on how to balance their committees.

See comment 16.

Additionally, the report should note that a committee of representatives may obtain "expert

advice" from individuals with scientific or technical expertise. For example, a scientific or technical expert may be invited to a meeting of the committee or its working groups to provide expert guidance to assist the representatives in formulating their advice to the federal government. Describing such options might help organizations and others to understand that representative membership can also be effective in providing useful, technically accurate, and unbiased advice to the federal government.

The following are GAO's comments on the Department of the Interior's letter dated March 18, 2004.

GAO Comments

1. This report states, as did the draft, that while our report focuses primarily on scientific and technical federal advisory committees, the limitations in guidance and the promising practices we identified pertaining to independence and balance are pertinent to federal advisory committees in general. This report and the draft also identified the wide range of issues addressed by federal advisory committees, including managing federal lands and natural resources.

2. The background section of the report and the draft acknowledged the FACA requirement that committees not be inappropriately influenced by the appointing authority or any special interest. However, the draft report also clearly stated that in addressing independence, our focus was on the requirements regarding individual conflicts of interest that are included in federal conflict-of-interest statutes, unless specifically noted otherwise. In our introduction, we state that "federal advisory committee members who are employees of the federal government must meet federal requirements pertaining to freedom from conflicts of interest—which we refer to in this report as independence—and committees as a whole must meet the requirements pertaining to balance." Thus, we use the term "independence" as shorthand for the conflict-of-interest requirements to which individual committee members must adhere. We further highlight the key provisions of the federal conflict-of-interest statutes that must be complied with, including a description of the ability of an individual who has a conflict of interest to nonetheless participate on a committee if granted a waiver. Alternatively, an individual may divest the financial interest.

   We note that all federal employees are prohibited not only from holding financial interests that conflict with the conscientious performance of duty, as Interior suggests in its comments, but also from engaging in outside employment or activities that conflict with their official duties and responsibilities. See 18 U.S.C. § 208, 5 C.F.R. §§ 2635.101(b)(2), and 2635.101(a)(10). Further, employees are also required to avoid any action that creates the appearance that they are violating the law or ethics standards. 5 C.F.R. § 2635.101(b)(14). It is precisely because these obligations are imposed only on employees that it is crucial to ensure that FACA committee members are appropriately characterized as "representatives" or special government employees. Both special

government employees and representatives should be evaluated for biases to ensure that the FACA committees as a whole are balanced. Special government employees must also be subject to a conflict-of-interest review, including an analysis of whether their nongovernment activities and employment present a conflict or create "the appearance that they are violating...ethics standards." 5 C.F.R. § 2635.101(b)(14).

3. We agree that the question of whether a member should participate in a particular committee function (or whether they should be appointed to a particular committee) is properly resolved on a case-by-base basis, evaluating the nature of the committee action or work and the nature of the financial interest involved. Further, the draft and final reports recognize that agencies may grant waivers to members to serve on advisory committees upon determining that either (1) the conflict is insignificant or (2) the need for the member's expertise outweighs the conflict. The draft and final reports also discuss some promising practices regarding the disclosure of such waivers to the public and among committee members.

4. The draft and final reports discuss in considerable detail information that can help agencies ensure committees are balanced and provide examples of promising practices that would better ensure the balance of advisory committees.

5. We agree that a relevant question for federal advisory committees is whether a committee has balance in terms of points of view to be represented and the functions to be performed. Our report provides examples of promising practices used by other agencies and the National Academies that can help agencies define and achieve an appropriate balance of points of view.

6. Our draft and final reports state that at the start of our review, Interior officials told us that they had begun to review their appointment classifications for the 115 advisory committees as a result of the November 2002 OGE study. The draft and final reports also state that the department has been reviewing the appointments to committees as their charters expire. We do indicate that in January 2004, Interior officials acknowledged that it was appropriate to change the nature of some appointments upon reexamination. This was the first time any results of the reviews were communicated to us. Further, Interior notified us of the decision to change the appointments to the

earthquake studies committee on January 16, 2004, subsequent to our meeting on January 12, 2004.

7. We revised the report to indicate that agencies do not conduct conflict-of-interest reviews for members appointed as representatives because conflict-of-interest reviews are only required for federal or special government employees. Thus, we removed any unintended implication that other agencies do more than the three we are reporting on in this report in terms of representative appointments. In our draft and final reports we indicate that the ethics screening vis-à-vis representatives done by one bureau of the department (Bureau of Land Management) is not sufficient to constitute a conflict-of-interest review for those appointed as special government employees. In this section, we are discussing those members who were appointed as representatives but who would be more appropriately appointed as special government employees.

8. We modified the language in the report to more clearly describe the authorities under which committees may be formed.

9. The draft and final reports define the two categories of appointments on page 1.

10. The draft and final reports state on page 1 that members of federal advisory committees may be appointed as (1) special government employees to provide advice on behalf of the government on the basis of their best judgment or (2) representatives to provide stakeholder advice. We do not take issue with representative appointments when the members are, in fact, appointed to represent a particular interest or view of an entity or group with an interest in the matter before the committees, and they are fully informed as to the point of view or interest they are to represent. Further, the reports state that Interior officials noted that many of their committees addressing federal land management issues are not scientific and technical in content and, in their view, are appropriately staffed with representative members. The reports do indicate that committees classified as scientific and technical, as well as others that address scientific and technical issues, are those for which advice on behalf of the government on the basis of members' best judgment is typically sought, rather than stakeholder advice. Interior has 11 committees with 288 members that are classified by the agency as scientific and technical committees in GSA's

FACA database, and some other committees not so classified also address scientific and technical issues.

11. We are not certain what Interior means in stating that "GAO's generalization that representation of fields of expertise is not appropriate ignores the importance of such representation to some committees." However, the comment does suggest that Interior continues to believe that it is appropriate to appoint members to represent their field of expertise as representatives, rather than as special government employees. We and OGE disagree with this interpretation of OGE's guidance on appointments to advisory committees. Representatives are to espouse a particular point of view of a party with an interest in the matter, whereas experts having specific expertise provide advice on behalf of the government on the basis of their best judgment. Thus, experts in various fields are more appropriately appointed as special government employees. (Subsequent to sending its comment letter, Interior clarified that the second sentence of this comment should read "However, we agree that agencies *should* have proper guidance in how and when to use such expertise.".)

12. We have removed the reference to January 2004 in this instance, reporting that Interior officials told us that they have begun to insert standard language in the charters regarding the ethics obligations of the members. See also comment 6.

13. On the basis of a January 2004 discussion with Interior officials, we understood the officials to say that in reviewing their appointment designations as committee charters expire, the agency was erring on the side of representative appointments when the information relevant to the committee was ambiguous on the issue of appointments. However, in its comments, Interior officials said they disagreed with our characterization of their previous comments, and we have deleted the statement from the report. In its comments, Interior officials said that the agency was likely to continue to appoint representatives to committees whose purpose is to advise the Secretary on the management of public lands or other resources as they are seeking the views of local stakeholders in these instances. As noted above, we do not take issue with representative appointments when the members are, in fact, appointed to represent a particular interest or view of an entity or group with an interest in the matter before the committees,

and they are fully informed as to the point of view or interest they are to represent.

14. Interior states that "GAO agrees that the statute authorizing the National Cooperative Geologic Mapping Advisory Committee 'calls for the committee to include…representatives,' but then goes on to state that the statute does not 'clearly and unambiguously call for these members to be appointed as representatives rather than special government employees.'." Interior then characterizes our statements as a contradiction and said that the Secretary of the Interior "reasonably may interpret such a statute by relying on its plain language….". In our draft and final reports, we indicate that the statute did not appear to clearly mandate that the members be appointed as representatives—that is, it may be using the term "representative" generically—and we further noted that is not clear what point of view the private-sector and academia members could be called upon to provide if appointed as representatives. We continue to believe this statute does not clearly and unambiguously call for representative appointments and that this example underscores the need for OGE clarification regarding the use of the term representative, as we recommend.

15. As the draft and final reports state, FACA requires that all committees be balanced overall in terms of both points of view represented and the function to be performed. In our view, in order for advisory committees to be effective, it is important that they are, and are perceived as being, balanced. The draft and final reports identify processes that include an evaluation of potential members' points of view *relevant to the subject matters advisory committees will consider* while focusing on the relevant expertise needed. The examples in the reports of agency processes that include such targeted evaluations of points of view ask potential members if they have made public statements or taken positions on the issue or matters the committee will consider, including expert legal testimony on the issue or matters. They also ask the potential members to identify and describe any reason they may be unable to provide impartial advice on matters before the committee and any reason their impartiality in the identified mater might be questioned. We disagree with Interior's view that these inquiries would be intrusive, of little practical utility, and would turn qualified individuals away from government service. We also disagree with Interior's view that we are saying that agencies need to understand all perceived biases of advisory committee members. As

shown above, the information identified as relevant to members' points of view is targeted and focuses on their points of view relevant to the subject matter to be considered. We disagree that such inquiries will turn qualified individuals away from government service, evidenced by the fact that the National Academies and EPA routinely obtain such relevant information from its prospective members. Finally, we recognize that representatives are placed on committees because of their stated stakeholder interests and do not assert that participation of representatives is improper.

16. We agree that committees, whether composed of representatives or special government employees, may invite outside experts to provide information or guidance. However, that does not affect the obligation agencies have to make appropriate decisions about appointing members as either representatives or special government employees.

Comments from the National Aeronautics and Space Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

National Aeronautics and
Space Administration
Office of the Administrator
Washington, DC 20546-0001

March 26, 2004

Ms. Robin M. Nazzaro
Director
Natural Resources and Environment
United States General Accounting Office
Room 2T23
441 G Street, NW
Washington, DC 20548

Dear Ms. Nazzaro:

NASA has reviewed the draft GAO report, *Federal Advisory Committees: Additional Guidance Could Help Agencies Better Ensure Independence and Balance (GAO-04-328)*. Advisory committees serve an important role for NASA and the agency appreciates the effort to strengthen the independence and balance of these committees.

See comment 1.

The overall conclusion that agencies could benefit from additional guidance to better ensure independence, balance, and transparency is sound. However, NASA is concerned about the implications of the finding that would limit the use of representative appointments for advisory committees to those persons who represent specific organizations, rather than a community at large (e.g., industry, education, or a particular field of scientific research). It is important that NASA retain the flexibility to use representatives who do not represent specific stakeholders. This is because individual stakeholder organizations would not necessarily be in a position to represent the overall interests of a broader community, and neither would their employees. Finally, since each community at large is itself comprised of individual organizations or stakeholders (for example, particular universities or trade groups, in the case of education), advisory committee members appointed as Special Government Employees rather than representatives would be precluded by the conflict of interest laws from participating in any discussion relating to their own organization, and by extension their community at large. This would effectively eliminate the perspective they were appointed to provide.

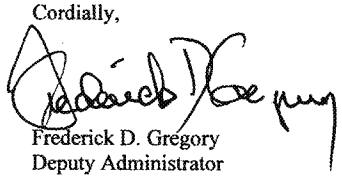
See comment 2.

In conclusion, in order to permit agencies to receive the views of entire communities, not just individual organizations, the draft recommendation should be modified to request that the Office of Government Ethics' guidance allow for the appointment of representatives of stakeholder communities as well as individual stakeholder organizations. Mr. Andrew Falcon, NASA's

Advisory Committee Management Officer, is available to discuss this matter further, and can be reached at (202) 358-2465.

I look forward to receiving a copy of the final report when available.

Cordially,



Frederick D. Gregory
Deputy Administrator

The following are GAO's comments on the National Aeronautics and Space Administration's letter dated March 26, 2004.

GAO Comments

1. NASA's comments support the appointment of federal advisory committee members as representative of their fields of expertise on the basis that some experts would not be able to serve as special government employees due to financial conflicts of interest. First, this view conflicts with OGE's and our view that representatives are not appropriately appointed to represent fields of expertise (see comment 2 below). Second, this view does not recognize that agencies may grant waivers to members to serve on advisory committees upon determining that either (1) the conflict is insignificant or (2) the need for the member's expertise outweighs the conflict.[1] Our draft and final reports discuss waivers and some promising practices regarding the disclosure of such waivers to the public and among committee members.

2. NASA also recommends that the OGE guidance allow for the appointment of representatives of "stakeholder communities" as well as individual stakeholder organizations. NASA identifies those that may represent a community as industry, education, or a particular field of expertise. We note that OGE guidance on representative appointments states that representatives may speak for stakeholders—that is, firms or an industry, labor or agriculture, or for any other recognizable group of persons with an interest in the matter under consideration. Thus, we believe that NASA can appoint experts as representatives to provide the views of, for example, the aerospace industry—if these experts are to provide stakeholder advice on matters in which the aerospace industry has an interest. If, however, NASA wants such experts to provide advice on behalf of the government on the basis of their individual and expert judgment, the appointments would be appropriately made as special government employees. These individuals would then be reviewed for potential financial conflicts of interest; if conflicts were identified, the conflicts would require mitigation. Regarding NASA's support for representatives providing the views of "stakeholder communities," we continue to believe that fields of expertise generally are not appropriately considered to be

[1]This view also provides support that OGE clarification on this issue is needed so that agencies can make appropriate decisions regarding representative appointments to federal advisory committees.

stakeholder communities. Specifically, fields of expertise may be defined as a stakeholder community only in instances where the subject matter a committee is addressing would have a particular impact on a field of expertise—for example, biologists, teachers, or doctors—but not in cases where the experts are called upon to provide expert advice on the basis of their individual judgment.

Comments from the Department of Energy

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

Department of Energy
Office of Science
Washington, DC 20585

Office of the Director

APR 0 1 2004

Dr. Robin M. Nazzaro
Director, Natural Resources
and Environment
General Accounting Office
Washington, D.C. 20548

Dear Dr. Nazzaro:

In response to your letter of March 3, 2004 inviting comment on the proposed report *Federal Advisory Committees Additional Guidance Could Help Agencies Better Ensure Independence and Balance* (the Report), the Department of Energy (DOE) is pleased to submit three general sets of comments:

See comment 1.

1. We are concerned about the implications of the "one-size-fits-all" approach that is being advocated in this Report. In particular, the special role that the Office of Science's six standing Advisory Committees play, within the U.S. scientific enterprise is not recognized and their overall effectiveness could be diminished if GAO recommendations are followed.

See comment 2.

2. The suggestions made by GAO to change the way that DOE selects Advisory Committee members should be implemented only if they would result in clearly defined benefits for DOE programs. Without that clear articulation of benefits, which we believe is absent in this Report, DOE should continue to select members according to our specific needs and circumstances.

See comment 3.

3. GAO's interpretation of the term "representative" is unpersuasive and would be an unsound basis of guidance for the Department.

See comment 1.

"One-Size-Fits-All" Approach

The Report correctly notes that DOE views members of its scientific Advisory Committees as representatives, in contrast to persons who provide individually-centered advice on behalf of the government who should become special government employees and concludes that this practice:

> ". . . exposes the relevant committees to potentially serious problems. Because representative members are not subject to reviews for potential conflicts of interest, allegation of conflicts of interest may call into question the integrity of the committee and jeopardize the credibility of the committee's work."

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See comment 1.

Report at 23.[1]

While this critique of government-wide Advisory Committees, generally, may be meritorious, applying it to DOE's Office of Science (SC) Advisory Committees appears to stem from a misunderstanding of SC's unique structure and how its scientific advisory committees assist in accomplishing DOE's vital national missions. This critique also fails to note the many self-regulating mechanisms inherent within the SC Advisory Committee structure that greatly diminish, or even eliminate, the potential for conflicts of interest.

DOE's basic research portfolio, which is managed by SC, is organized according to *scientific disciplines* (physics, chemistry, mathematics, etc.). This organizational structure – which is manifested through SC's budget categories, office structures, personnel assignments, etc. – is critical to understanding why SC's Advisory Committee members are inherently representative.

The reason we say this is that SC's Advisory Committees are focused on the health of specific scientific disciplines. It might surprise you to learn that although more than 50% of SC's research dollars go to DOE's national laboratories, only 15% of the total membership of SC's Advisory Committees comes from those laboratories. The majority of representatives come from universities (65%), non-profits and other parts of the U.S. scientific community who have a stronger interest in the overall health of the disciplines that they represent than in the institutions that perform the research. As an example, the Nuclear Science Advisory Committee's charter states:

"Committee members shall be appointed with a view towards achieving balanced representation of the various subfields involved in basic nuclear science research by the Secretary of Energy following nomination by the Director, Office of Science, Department of Energy, with concurrence of the Assistant Director, Mathematical and Physical Sciences Directorate, National Science Foundation."

As a final note on this subject, we would invite you to speak individually with the SC Advisory Committee Chairs and Members and ask them if they believe that a Member's potential conflict of interest would escape the attention of other

See comment 4.

[1] DOE does not uniformly conclude that members of its advisory committees are "representative". When a member is selected for his or her expertise, as contrasted to being a representative, the member is appointed as a special government employee. For example, earlier this year, the Department determined that several individuals who were to be appointed to the Environmental Management Advisory Committee were selected because of their expertise in certain areas. These individuals will be serving on this Committee as special government employees.

See comment 2.

Committee Members or the SC professional program managers for very long. We believe you would find that conflicts of interest are simply not an issue for the reasons cited above.

Selection of Committee Membership
The Report urges agencies to obtain Committee members via a public process such as Federal Register notice. Here too, we believe that a one-size-fits-all approach is inappropriate.

In certain areas pertinent to its Advisory Committees, DOE funds and/or directly conducts all or virtually all United States research. This is particularly true for SC's Advisory Committees in Nuclear Physics, Fusion and High Energy Physics. These Committees provide advice to SC programs that support 90-100% of total Federal R&D in these scientific disciplines.

Their knowledge of their fields is such that the SC program managers and Advisory Committee Members know the research areas and credentials of all of the leading scientists in their field. In addition, the program managers are often aware of the personal biases, work ethic and degree of frankness that key players may bring to the Advisory Committee so that they are especially well qualified to select a balanced committee. A public selection process would not result in the selection of more appropriate members nor a more balanced committee. For this reason alone, DOE's current selection practice should be maintained.

But there is another compelling reason that DOE's processes for selection of Advisory Committees should not be changed – neither GAO nor any other study group has ever provided a rationale for change that would result in higher quality advice from the SC Advisory Committees. SC Advisory Committees, for the most part, have been in existence for decades. They perform their functions admirably and it is deemed a great honor within the U.S. scientific community to serve – without compensation – on these Committees. To our knowledge, no one who understands how they truly function has ever asserted that these Committees are anything less then superb and appropriate for the work that they do and the role that they perform within DOE and the U.S. scientific enterprise. Changing them for change's sake (or to force uniformity upon Federal advisory committees with widely ranging purposes) would be a serious error and could have significant (and adverse) consequences for the way that science is conducted in the United States.

Meaning of the Term "Representative"
The Report, at 21, states that "Office of Government Ethics guidance is overly-broad in that it states representatives may speak for an industry, or for labor or agriculture, or for any other recognizable group of persons including, on occasion, the public at large. We are concerned about the implications of this statement."

See comment 3.

DOE has certain Advisory Committees that it views as clearly representational in that they do speak for industries such as the National Coal Council and the National Petroleum Council, all of whose members are affiliated with energy companies or entities that have an organizational interest in the matters before the Councils. The Environmental Management Site Specific Advisory Board, which has many members who speak for the local public at large, was established to serve as a channel for communicating advice from the communities impacted by DOE activities. DOE is concerned that the report inadvertently and unnecessarily calls into question the use of representatives on these committees.

The Report, at 22, states that "at times the terms 'represent' or 'representative', when included in legislation or executive orders regarding the membership of advisory committees, does not always clearly indicate that the members are to be appointed to serve as representatives; sometimes these terms are used to define committee composition or balance." The Report does not cite the authority for its statement.

DOE is not persuaded of the soundness of this view as a source of guidance for the Department. Congress or the President use words like "expert" or "expertise" where it is intended for the members to be appointed as special government employees. Agencies should not be called on in this area to violate one of the basic rules of statutory construction and thereby to question the plain meaning of words.

Sincerely,

Raymond L. Orbach
Director
Office of Science

The following are GAO's comments on the Department of Energy's letter dated April 1, 2004.

GAO Comments

1. The first issue that Energy identifies as being of concern vis-à-vis its perception of "GAO's advocacy of a 'one-size-fits-all' approach" is, in essence, the governmentwide application of OGE's criteria for representative appointments. That is, while Energy does not disagree that it may be generally inappropriate to appoint advisory committee members to represent various fields of expertise, the department believes it is appropriate for its Office of Science to do so on the basis of the agency's "unique structure." Specifically, Energy says that the Office of Science's advisory committee members are inherently representative because the department's basic research portfolio is managed according to scientific disciplines (physics, chemistry, mathematics) and the related advisory committees are "focused on the health of specific scientific disciplines." In our view, the department's research structure is not unique and does not provide a basis for appointing experts providing advice on the basis of their best judgment as representatives. For example, both the National Science Foundation and NASA manage research portfolios by scientific disciplines, and they generally appoint members to their scientific and technical advisory committees appropriately as special government employees.[1] We believe Energy's comments support our view that OGE needs to clarify its guidance on representative appointments.

2. The second issue that Energy views as our advocacy of a "one-size-fits-all" approach concerns obtaining input on the "selection of committee membership." Energy does not specify whether it is addressing (1) nominations for committee membership from the public, (2) comments on proposed committee membership, or (3) both of these practices. In any event, the draft and final reports identify these as promising practices that are particularly relevant to those committees addressing sensitive or controversial issues, and not as practices that should be applied to all committees.

[1]NASA's comments in response to this report indicate that NASA does, at least in some cases, appoint members to represent their expertise. Unlike Energy, NASA cites issues related to conflicts of interest as a basis for doing so.

3. Energy states that our interpretation of the term representative is unpersuasive and would be an unsound basis of guidance for the department. In elaborating on this perspective, the department makes two points. First, the department states that it has certain advisory committees, such as the National Coal Council and the National Petroleum Council, that it views as clearly representational in that the members do speak for energy companies or entities that have an organizational interest in the matter. Energy expresses concern that the report inadvertently and unnecessarily calls into question the use of representatives on these committees. We disagree. The draft and final reports state on page 1 that members of federal advisory committees may be appointed as (1) special government employees to provide advice on behalf of the government on the basis of their best judgment or (2) representatives to provide stakeholder advice. We do not take issue with representative appointments when the members are, in fact, appointed to represent a particular interest or view of an entity or group with an interest in the matter before the committees, and they are fully informed as to the point of view or interest they are to represent. Second, Energy questions our view that use of the terms "represent" or "representative" regarding the membership of advisory committees does not always clearly indicate that the members are to be appointed to serve as representatives. In its comments on the draft report, OGE stated that its guidance does not imply that any use of the word "represent" or its cognate forms in a statute or other document means that the members of the committees are not special government employees. Further, OGE stated that its guidance makes clear that careful attention to all relevant factors is required in order to determine whether the committee members are actually intended to serve as representatives of interest groups. While OGE disagreed with our recommendation that its guidance needed to be clarified to state that the term representative in statutes and charters may be used more generically to identify the appropriate balance of points of view or expertise and may not be specifying that representative appointments be made, we believe Energy's comments on this point provide additional support for our recommendation.

4. The draft and final reports state that USDA, Energy, and Interior appoint most or all of the members to their federal advisory committees as representatives. We believe this statement accurately describes Energy's appointments. For example, our draft and final reports state that in April 2003, Energy's Acting Assistant General Counsel for General Law told us that all but one of the department's

committees use only representatives members; we indicated that this one committee expired in June 2003. In its comments on the draft report, Energy identifies another committee for which DOE appointed several members in 2004 as special government employees.

GAO Contacts and Staff Acknowledgments

GAO Contacts

Robin Nazzaro, (202) 512-3841
Christine Fishkin, (202) 512-6895

Staff Acknowledgments

In addition to those individuals named above, Lindsay Bach, Ross Campbell, Bernice Dawson, John Delicath, Judy Pagano, and Amy Webbink made key contributions to this report.

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(3) The licensee submits a letter of intent by December 31, 2005, stating its intent to transition to 10 CFR 50.48(c).

After December 31, 2005, as addressed in (3) above, this enforcement discretion for implementation of corrective actions for existing identified noncompliances will not be available and the requirements of 10 CFR 50.48(b) (and any other requirements in fire protection license conditions) will be enforced in accordance with normal enforcement practices.

Dated at Rockville, MD, this 11th day of January, 2005.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 05–887 Filed 1–13–05; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting Notice

AGENCY: Nuclear Regulatory Commission.

DATE: Week of January 17, 2005.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

ADDITIONAL MATTERS TO BE CONSIDERED:

Week of January 17, 2005

Tuesday, January 18, 2005

9:55 a.m. Affirmation Session (Public Meeting) (Tentative).

a. System Energy Resources Inc. (Early Site Permit for Grand Gulf Nuclear Site), Docket Number 52–009, Appeal by National Association for the Advancement of Colored People—Claiborne County, Mississippi Branch, Nuclear Information Service, Public Citizen, and Mississippi Chapter of the Sierra Club from LBP–04–19. (Tentative).

b. Louisiana Energy Services, L.P. (National Enrichment Facility) (Tentative).

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Dave Gamberoni, (301) 415–1651.

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html.*

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Dated: January 11, 2005.

Dave Gamberoni,

Office of the Secretary.

[FR Doc. 05–890 Filed 1–12–05; 9:32 am]

BILLING CODE 7590–01–M

OFFICE OF MANAGEMENT AND BUDGET

Final Information Quality Bulletin for Peer Review

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Final bulletin.

SUMMARY: On December 16, 2004, the Office of Management and Budget (OMB), in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review to the heads of departments and agencies (available at *http://www.whitehouse.gov/omb/memoranda/fy2005/m05–03.html*). This new guidance is designed to realize the benefits of meaningful peer review of the most important science disseminated by the Federal Government. It is part of an ongoing effort to improve the quality, objectivity, utility, and integrity of information disseminated by the Federal Government to the public. This final bulletin has benefited from an extensive stakeholder process. OMB originally requested comment on its "Proposed Bulletin on Peer Review and Information Quality," published in the **Federal Register** on September 15, 2003. OMB received 187 public comments during the comment period (available at *http://www.whitehouse.gov/omb/inforeg/2003iq/iq_list.html*). In addition, to improve the draft Bulletin, OMB encouraged federal agencies to sponsor a public workshop at the National Academy of Sciences (NAS). The NAS workshop (November 18, 2003, at the National Academies in Washington, DC) attracted several hundred participants, including leaders in the scientific community (available at *http://www7.nationalacademies.org/stl/STL_Peer_Review_Agenda.html*). OMB also participated in outreach activities with major scientific organizations and societies that had expressed specific interest in the draft Bulletin. A formal interagency review of the draft Bulletin, resulting in detailed comments from numerous Federal departments and agencies, was undertaken in collaboration with the White House Office of Science and Technology Policy. In light of the substantial interest in the Bulletin, including a wide range of constructive criticisms of the initial draft, OMB decided to issue a revised draft for further comment. This revised draft was published in the **Federal Register** on April 28, 2004, and solicited a second round of public comment. The revised draft stimulated a much smaller number of comments (57) (available at: *http://www.whitehouse.gov/omb/inforeg/peer2004/list_peer2004.html*). OMB's response to the additional criticisms, suggestions, and refinements offered for consideration is available at: *http://www.whitehouse.gov/omb/inforeg/peer2004/peer_response.pdf.* The final Bulletin includes refinements that strike a balance among the diverse perspectives expressed during the comment period. Part I of the **SUPPLEMENTARY INFORMATION** below provides background. Part II provides the text of the final Bulletin.

DATES: The requirements of this Bulletin, with the exception of those in Section V (Peer Review Planning), apply to information disseminated on or after June 16, 2005. However, they do not apply to information for which an agency has already provided a draft report and an associated charge to peer reviewers. The requirements in Section V regarding "highly influential scientific assessments" are effective June 16, 2005. The requirements in Section V regarding "influential scientific information" are effective December 16, 2005.

FOR FURTHER INFORMATION CONTACT: Dr. Margo Schwab, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., New Executive Office Building, Room 10201, Washington, DC 20503. Telephone (202) 395–5647 or email: *OMB_peer_review@omb.eop.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

This Bulletin establishes that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal government. We published a proposed Bulletin on September 15, 2003. Based on public comments, we published a revised proposal for additional comment on April 28, 2004. We are now finalizing the April version, with minor revisions responsive to the public's comments.

The purpose of the Bulletin is to enhance the quality and credibility of the government's scientific information. We recognize that different types of peer review are appropriate for different types of information. Under this Bulletin, agencies are granted broad discretion to weigh the benefits and costs of using a particular peer review mechanism for a specific information product. The selection of an appropriate peer review mechanism for scientific information is left to the agency's discretion. Various types of information are exempted from the requirements of this Bulletin, including time-sensitive health and safety determinations, in order to ensure that peer review does not unduly delay the release of urgent findings.

This Bulletin also applies stricter minimum requirements for the peer review of highly influential scientific assessments, which are a subset of influential scientific information. A scientific assessment is an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. To ensure that the Bulletin is not too costly or rigid, these requirements for more intensive peer review apply only to the more important scientific assessments disseminated by the Federal government.

Even for these highly influential scientific assessments, the Bulletin leaves significant discretion to the agency formulating the peer review plan. In general, an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s). The agency selecting peer reviewers must ensure that the reviewers possess the necessary expertise. In addition, the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency. This Bulletin requires agencies to adopt or adapt the committee selection policies employed by the National Academy of Sciences (NAS) [1] when selecting peer reviewers who are not government employees. Those that are government employees are subject to federal ethics requirements. The use of a transparent process, coupled with the selection of qualified and independent peer reviewers, should improve the quality of government science while promoting public confidence in the integrity of the government's scientific products.

Peer Review

Peer review is one of the important procedures used to ensure that the quality of published information meets the standards of the scientific and technical community. It is a form of deliberation involving an exchange of judgments about the appropriateness of methods and the strength of the author's inferences.[2] Peer review involves the review of a draft product for quality by specialists in the field who were not involved in producing the draft.

The peer reviewer's report is an evaluation or critique that is used by the authors of the draft to improve the product. Peer review typically evaluates the clarity of hypotheses, the validity of the research design, the quality of data collection procedures, the robustness of the methods employed, the appropriateness of the methods for the hypotheses being tested, the extent to which the conclusions follow from the analysis, and the strengths and limitations of the overall product.

Peer review has diverse purposes. Editors of scientific journals use reviewer comments to help determine whether a draft scientific article is of sufficient quality, importance, and interest to a field of study to justify publication. Research funding organizations often use peer review to evaluate research proposals. In addition, some Federal agencies make use of peer review to obtain evaluations of draft information that contains important scientific determinations.

Peer review should not be confused with public comment and other stakeholder processes. The selection of participants in a peer review is based on expertise, with due consideration of independence and conflict of interest. Furthermore, notice-and-comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as some experts—especially those most knowledgeable in a field—may not file public comments with Federal agencies.

The critique provided by a peer review often suggests ways to clarify assumptions, findings, and conclusions. For instance, peer reviews can filter out biases and identify oversights, omissions, and inconsistencies.[3] Peer review also may encourage authors to more fully acknowledge limitations and uncertainties. In some cases, reviewers might recommend major changes to the draft, such as refinement of hypotheses, reconsideration of research design, modifications of data collection or analysis methods, or alternative conclusions. However, peer review does not always lead to specific modifications in the draft product. In some cases, a draft is in excellent shape prior to being submitted for review. In others, the authors do not concur with changes suggested by one or more reviewers.

Peer review may take a variety of forms, depending upon the nature and importance of the product. For example, the reviewers may represent one scientific discipline or a variety of disciplines; the number of reviewers may range from a few to more than a dozen; the names of each reviewer may be disclosed publicly or may remain anonymous (*e.g.*, to encourage candor); the reviewers may be blinded to the authors of the report or the names of the authors may be disclosed to the reviewers; the reviewers may prepare individual reports or a panel of reviewers may be constituted to produce a collaborative report; panels may do their work electronically or they may meet together in person to discuss and prepare their evaluations; and reviewers may be compensated for their work or they may donate their time as a

[1] National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: *http://www.nationalacademies.org/coi/index.html.*

[2] Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decision Making*, Carnegie Commission, New York, 1993: 75.

[3] William W. Lowrance, *Modern Science and Human Values*, Oxford University Press, New York, NY 1985: 85.

contribution to science or public service.

For large, complex reports, different reviewers may be assigned to different chapters or topics. Such reports may be reviewed in stages, sometimes with confidential reviews that precede a public process of panel review. As part of government-sponsored peer review, there may be opportunity for written and/or oral public comments on the draft product.

The results of peer review are often only one of the criteria used to make decisions about journal publication, grant funding, and information dissemination. For instance, the editors of scientific journals (rather than the peer reviewers) make final decisions about a manuscript's appropriateness for publication based on a variety of considerations. In research-funding decisions, the reports of peer reviewers often play an important role, but the final decisions about funding are often made by accountable officials based on a variety of considerations. Similarly, when a government agency sponsors peer review of its own draft documents, the peer review reports are an important factor in information dissemination decisions but rarely are the sole consideration. Agencies are not expected to cede their discretion with regard to dissemination or use of information to peer reviewers; accountable agency officials must make the final decisions.

The Need for Stronger Peer Review Policies

There are a multiplicity of science advisory procedures used at Federal agencies and across the wide variety of scientific products prepared by agencies.[4] In response to congressional inquiry, the U.S. General Accounting Office (now the Government Accountability Office) documented the variability in both the definition and implementation of peer review across agencies.[5] The Carnegie Commission on Science, Technology and Government[6] has highlighted the importance of "internal" scientific advice (within the agency) and "external" advice (through scientific advisory boards and other mechanisms).

A wide variety of authorities have argued that peer review practices at federal agencies need to be strengthened.[7] Some arguments focus on specific types of scientific products (*e.g.*, assessments of health, safety and environmental hazards).[8] The Congressional/Presidential Commission on Risk Assessment and Risk Management suggests that "peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information."[9]

Some agencies have formal peer review policies, while others do not. Even agencies that have such policies do not always follow them prior to the release of important scientific products.

Prior to the development of this Bulletin, there were no government-wide standards concerning when peer review is required and, if required, what type of peer review processes are appropriate. No formal interagency mechanism existed to foster cross-agency sharing of experiences with peer review practices and policies. Despite the importance of peer review for the credibility of agency scientific products, the public lacked a consistent way to determine when an important scientific information product is being developed by an agency, the type of peer review planned for that product, or whether there would be an opportunity to provide comments and data to the reviewers.

This Bulletin establishes minimum standards for when peer review is required for scientific information and the types of peer review that should be considered by agencies in different circumstances. It also establishes a transparent process for public disclosure of peer review planning, including a Web-accessible description of the peer review plan that the agency has developed for each of its forthcoming influential scientific disseminations.

Legal Authority for the Bulletin

This Bulletin is issued under the Information Quality Act and OMB's general authorities to oversee the quality of agency information, analyses, and regulatory actions. In the Information Quality Act, Congress directed OMB to issue guidelines to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information" disseminated by Federal agencies. Public Law No. 106–554, § 515(a). The Information Quality Act was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, which requires OMB, among other things, to "develop and oversee the implementation of policies, principles, standards, and guidelines to * * * apply to Federal agency dissemination of public information." In addition, Executive Order 12866, 58 FR 51,735 (Oct. 4, 1993), establishes that OIRA is "the repository of expertise concerning regulatory issues," and it directs OMB to provide guidance to the agencies on regulatory planning. E.O. 12866, § 2(b). The Order also requires that "[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information." E.O. 12866, § 1(b)(7). Finally, OMB has authority in certain circumstances to manage the agencies under the purview of the President's Constitutional authority to supervise the unitary Executive Branch. All of these authorities support this Bulletin.

The Requirements of This Bulletin

This Bulletin addresses peer review of scientific information disseminations that contain findings or conclusions that represent the official position of one or more agencies of the Federal government.

Section I: Definitions

Section I provides definitions that are central to this Bulletin. Several terms are identical to or based on those used in OMB's government-wide information quality guidelines, 67 FR 8452 (Feb. 22, 2002), and the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

[4] Sheila Jasanoff, *The Fifth Branch: Science Advisors as Policy Makers*, Harvard University Press, Boston, 1990.

[5] U.S. General Accounting Office, *Federal Research: Peer Review Practices at Federal Agencies Vary*, GAO/RCED–99–99, Washington, DC, 1999.

[6] Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decision Making*, Carnegie Commission, New York, 1993: 90.

[7] National Academy of Sciences, *Peer Review in the Department of Energy—Office of Science and Technology*, Interim Report, National Academy Press, Washington, DC, 1997; National Academy of Sciences, *Peer Review in Environmental Technology Development: The Department of Energy—Office of Science and Technology*, National Academy Press, Washington, DC, 1998; National Academy of Sciences, *Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices*, National Academy Press, Washington, DC, 2000; U.S. General Accounting Office, *EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance*, GAO–01–536, Washington, DC, 2001; U.S. Environmental Protection Agency, Office of Inspector General, *Pilot Study: Science in Support of Rulemaking 2003*–P–00003, Washington, DC, 2002; Carnegie Commission on Science, Technology, and Government, *In the National Interest: The Federal Government in the Reform of K–12 Math and Science Education*, Carnegie Commission, New York, 1991; U.S. General Accounting Office, *Endangered Species Program: Information on How Funds Are Allocated and What Activities are Emphasized*, GAO–02–581, Washington, DC, 2002.

[8] National Research Council, *Science and Judgment in Risk Assessment*, National Academy Press, Washington, DC, 1994.

[9] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, Volume 2, *Risk Assessment and Risk Management in Regulatory Decision-Making*, 1997:103.

The term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA).

The term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. 3502(1).

The term "Information Quality Act" means Section 515 of Public Law 106–554 (Pub. L. No. 106–554, § 515, 114 Stat. 2763, 2763A–153–154 (2000)).

The term "dissemination" means agency initiated or sponsored distribution of information to the public. Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra-or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act, or similar laws. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. In the context of this Bulletin, the definition of "dissemination" modifies the definition in OMB's government-wide information quality guidelines to address the need for peer review prior to official dissemination of the information product. Accordingly, under this Bulletin, "dissemination" also excludes information distributed for peer review in compliance with this Bulletin or shared confidentially with scientific colleagues, provided that the distributing agency includes an appropriate and clear disclaimer on the information, as explained more fully below. Finally, the Bulletin does not directly cover information supplied to the government by third parties (*e.g.*, studies by private consultants, companies and private, non-profit organizations, or research institutions such as universities). However, if an agency plans to disseminate information supplied by a third party (*e.g.*, using this information as the basis for an agency's factual determination that a particular behavior causes a disease), the requirements of the Bulletin apply, if the dissemination is "influential".

In cases where a draft report or other information is released by an agency solely for purposes of peer review, a question may arise as to whether the draft report constitutes an official "dissemination" under information-quality guidelines. Section I instructs agencies to make this clear by presenting the following disclaimer in the report:

> This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by [the agency]. It does not represent and should not be construed to represent any agency determination or policy.

In cases where the information is highly relevant to specific policy or regulatory deliberations, this disclaimer shall appear on each page of a draft report. Agencies also shall discourage state, local, international and private organizations from using information in draft reports that are undergoing peer review. Draft influential scientific information presented at scientific meetings or shared confidentially with colleagues for scientific input prior to peer review shall include the disclaimer: "The Findings and Conclusions in This Report (Presentation) Have Not Been Formally Disseminated by [The Agency] and Should Not Be Construed to Represent Any Agency Determination or Policy."

An information product is not covered by the Bulletin unless it represents an official view of one or more departments or agencies of the Federal government. Accordingly, for the purposes of this Bulletin, "dissemination" excludes research produced by government-funded scientists (*e.g.*, those supported extramurally or intramurally by Federal agencies or those working in state or local governments with Federal support) if that information is not represented as the views of a department or agency (*i.e.*, they are not official government disseminations). For influential scientific information that does not have the imprimatur of the Federal government, scientists employed by the Federal government are required to include in their information product a clear disclaimer that "the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency." A similar disclaimer is advised for non-government employees who publish government-funded research.

For the purposes of the peer review Bulletin, the term "scientific information" means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a Web page, but does not include the provision of hyperlinks on a Web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered.

The term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. In the term "influential scientific information," the term "influential" should be interpreted consistently with OMB's government-wide information quality guidelines and the information quality guidelines of the agency. Information dissemination can have a significant economic impact even if it is not part of a rulemaking. For instance, the economic viability of a technology can be influenced by the government's characterization of its attributes. Alternatively, the Federal government's assessment of risk can directly or indirectly influence the response actions of state and local agencies or international bodies.

One type of scientific information is a scientific assessment. For the purposes of this Bulletin, the term "scientific assessment" means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments. Such assessments often draw upon knowledge from multiple disciplines. Typically, the data and models used in scientific assessments have already been subject to some form of peer review (*e.g.*, refereed journal peer review or peer review under Section II of this Bulletin).

Section II: Peer Review of Influential Scientific Information

Section II requires each agency to subject "influential" scientific information to peer review prior to dissemination. For dissemination of

influential scientific information, Section II provides agencies broad discretion in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers. Agencies are directed to chose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review.

The National Academy of Public Administration suggests that the intensity of peer review should be commensurate with the significance of the information being disseminated and the likely implications for policy decisions.[10] Furthermore, agencies need to consider tradeoffs between depth of peer review and timeliness.[11] More rigorous peer review is necessary for information that is based on novel methods or presents complex challenges for interpretation. Furthermore, the need for rigorous peer review is greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact.

This tradeoff can be considered in a benefit-cost framework. The costs of peer review include both the direct costs of the peer review activity and those stemming from potential delay in government and private actions that can result from peer review. The benefits of peer review are equally clear: the insights offered by peer reviewers may lead to policy with more benefits and/or fewer costs. In addition to contributing to strong science, peer review, if performed fairly and rigorously, can build consensus among stakeholders and reduce the temptation for courts and legislators to second-guess or overturn agency actions.[12] While it will not always be easy for agencies to quantify the benefits and costs of peer review, agencies are encouraged to approach peer review from a benefit-cost perspective.

Regardless of the peer review mechanism chosen, agencies should strive to ensure that their peer review practices are characterized by both scientific integrity and process integrity. "Scientific integrity," in the context of peer review, refers to such issues as "expertise and balance of the panel members; the identification of the scientific issues and clarity of the charge to the panel; the quality, focus and depth of the discussion of the issues by the panel; the rationale and supportability of the panel's findings; and the accuracy and clarity of the panel report." "Process integrity" includes such issues as "transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement," and adherence to defined procedures.[13]

When deciding what type of peer review mechanism is appropriate for a specific information product, agencies will need to consider at least the following issues: Individual versus panel review; timing; scope of the review; selection of reviewers; disclosure and attribution; public participation; disposition of reviewer comments; and adequacy of prior peer review.

Individual Versus Panel Review

Letter reviews by several experts generally will be more expeditious than convening a panel of experts. Individual letter reviews are more appropriate when a draft document covers only one discipline or when premature disclosure of a sensitive report to a public panel could cause harm to government or private interests. When time and resources warrant, panels are preferable, as they tend to be more deliberative than individual letter reviews and the reviewers can learn from each other. There are also multi-stage processes in which confidential letter reviews are conducted prior to release of a draft document for public notice and comment, followed by a formal panel review. These more rigorous and expensive processes are particularly valuable for highly complex, multidisciplinary, and more important documents, especially those that are novel or precedent-setting.

Timing of Peer Review

As a general rule, it is most useful to consult with peers early in the process of producing information. For example, in the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results. "Early" peer review occurs in time to "focus attention on data inadequacies in time for corrections.

When an information product is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options so that any technical corrections can be made before the agency becomes invested in a specific approach or the positions of interest groups have hardened. If review occurs too late, it is unlikely to contribute to the course of a rulemaking. Furthermore, investing in a more rigorous peer review early in the process "may provide net benefit by reducing the prospect of challenges to a regulation that later may trigger time consuming and resource-draining litigation." [14]

Scope of the Review

The "charge" contains the instructions to the peer reviewers regarding the objective of the peer review and the specific advice sought. The importance of the information, which shapes the goal of the peer review, influences the charge. For instance, the goal of the review might be to determine the utility of a body of literature for drawing certain conclusions about the feasibility of a technology or the safety of a product. In this context, an agency might ask reviewers to determine the relevance of conclusions drawn in one context for other contexts (*e.g.*, different exposure conditions or patient populations).

The charge to the reviewers should be determined in advance of the selection of the reviewers. In drafting the charge, it is important to remember the strengths and limitations of peer review. Peer review is most powerful when the charge is specific and steers the reviewers to specific technical questions while also directing reviewers to offer a broad evaluation of the overall product.

Uncertainty is inherent in science, and in many cases individual studies do not produce conclusive evidence. Thus, when an agency generates a scientific

[10] National Academy of Public Administration, Setting Priorities, Getting Results: A New Direction for EPA, National Academy Press, Washington, DC, 1995:23.

[11] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997.

[12] Mark R. Powell, *Science at EPA: Information in the Regulatory Process*, Resources for the Future, Washington, DC, 1999: 148, 176; Sheila Jasanoff, *The Fifth Branch: Science Advisors as Policy Makers*, Harvard University Press, Boston, 1990: 242.

[13] ILSI Risk Sciences Institute, "Policies and Procedures: Model Peer Review Center of Excellence," 2002: 4. Available at *http://rsi.ilsi.org/file/Policies&Procedures.pdf*.

[14] Fred Anderson, Mary Ann Chirba Martin, E Donald Elliott, Cynthia Farina, Ernest Gellhorn, John D. Graham, C. Boyden Gray, Jeffrey Holmstead, Ronald M. Levin, Lars Noah, Katherine Rhyne, Jonathan Baert Wiener, "Regulatory Improvement Legislation: Risk Assessment, Cost-Benefit Analysis, and Judicial Review," *Duke Environmental Law and Policy Forum*, Fall 2000, vol. XI (1): 132.

assessment, it is presenting its scientific judgment about the accumulated evidence rather than scientific fact.[15] Specialists attempt to reach a consensus by weighing the accumulated evidence. Peer reviewers can make an important contribution by distinguishing scientific facts from professional judgments. Furthermore, where appropriate, reviewers should be asked to provide advice on the reasonableness of judgments made from the scientific evidence. However, the charge should make clear that the reviewers are not to provide advice on the policy (*e.g.*, the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis). Such considerations are the purview of the government.[16]

The charge should ask that peer reviewers ensure that scientific uncertainties are clearly identified and characterized. Since not all uncertainties have an equal effect on the conclusions drawn, reviewers should be asked to ensure that the potential implications of the uncertainties for the technical conclusions drawn are clear. In addition, peer reviewers might be asked to consider value-of-information analyses that identify whether more research is likely to decrease key uncertainties.[17] Value-of-information analysis was suggested for this purpose in the report of the Presidential/Congressional Commission on Risk Assessment and Risk Management.[18] A description of additional research that would appreciably influence the conclusions of the assessment can help an agency assess and target subsequent efforts.

Selection of Reviewers

Expertise. The most important factor in selecting reviewers is expertise: ensuring that the selected reviewer has the knowledge, experience, and skills necessary to perform the review. Agencies shall ensure that, in cases where the document being reviewed spans a variety of scientific disciplines or areas of technical expertise, reviewers who represent the necessary spectrum of knowledge are chosen. For instance, expertise in applied mathematics and statistics is essential in the review of models, thereby allowing an audit of calculations and claims of significance and robustness based on the numeric data.[19] For some reviews, evaluation of biological plausibility is as important as statistical modeling. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

Balance. While expertise is the primary consideration, reviewers should also be selected to represent a diversity of scientific perspectives relevant to the subject. On most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of the available literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review. Indeed, as a final layer of review, some organizations (*e.g.*, the National Academy of Sciences) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports. The NAS policy on committee composition and balance[20] highlights important considerations associated with perspective, bias, and objectivity.

Independence. In its narrowest sense, independence in a reviewer means that the reviewer was not involved in producing the draft document to be reviewed. However, for peer review of some documents, a broader view of independence is necessary to assure credibility of the process. Reviewers are generally not employed by the agency or office producing the document. As the National Academy of Sciences has stated, "external experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns."[21] The Carnegie Commission on Science, Technology, and Government notes that "external science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a range of issues."[22] However, the choice of reviewers requires a case-by-case analysis. Reviewers employed by other Federal and state agencies may possess unique or indispensable expertise.

A related issue is whether government-funded scientists in universities and consulting firms have sufficient independence from the federal agencies that support their work to be appropriate peer reviewers for those agencies.[23] This concern can be mitigated in situations where the scientist initiates the hypothesis to be tested or the method to be developed, which effectively creates a buffer between the scientist and the agency. When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects. This contrasts, for example, to a situation in which a scientist has a consulting or contractual arrangement with the agency or office sponsoring a peer review. Likewise, when the agency and a researcher work together (*e.g.*, through a cooperative agreement) to design or implement a study, there is less independence from the agency. Furthermore, if a scientist has repeatedly served as a reviewer for the same agency, some may question whether that scientist is sufficiently independent from the agency to be employed as a peer reviewer on agency-sponsored projects.

As the foregoing suggests, independence poses a complex set of questions that must be considered by agencies when peer reviewers are selected. In general, agencies shall make an effort to rotate peer review responsibilities across the available pool of qualified reviewers, recognizing that in some cases repeated service by the same reviewer is needed because of essential expertise.

Some agencies have built entire organizations to provide independent scientific advice while other agencies tend to employ ad hoc scientific panels on specific issues. Respect for the independence of reviewers may be enhanced if an agency collects names of potential reviewers (based on considerations of expertise and reputation for objectivity) from the

[15] Mark R. Powell, *Science at EPA: Information in the Regulatory Process*, Resources for the Future, Washington, DC, 1999: 139.

[16] Ibid.

[17] Granger Morgan and Max Henrion, "The Value of Knowing How Little You Know," *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press, 1990: 307.

[18] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997, Volume 1: 39, Volume 2: 91.

[19] William W. Lowrance, *Modern Science and Human Values*, Oxford University Press, New York, NY 1985: 86.

[20] National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: *http://www.nationalacademies.org/coi/index.html.*

[21] National Research Council, *Peer Review in Environmental Technology Development Programs: The Department of Energy's Office of Science and Technology*, National Academy Press, Washington, DC, 1998: 3.

[22] Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decision Making*, Carnegie Commission, New York, 1993: 90.

[23] Lars Noah, "Scientific 'Republicanism': Expert Peer Review and the Quest for Regulatory Deliberation, *Emory Law Journal*, Atlanta, Fall 2000:1066.

public, including scientific or professional societies. The Department of Energy's use of the American Society of Mechanical Engineers to identify potential peer reviewers from a variety of different scientific societies provides an example of how professional societies can assist in the development of an independent peer review panel.[24]

Conflict of Interest. The National Academy of Sciences defines "conflict of interest" as any financial or other interest that conflicts with the service of an individual on the review panel because it could impair the individual's objectivity or could create an unfair competitive advantage for a person or organization.[25] This standard provides a useful benchmark for agencies to consider in selecting peer reviewers. Agencies shall make a special effort to examine prospective reviewers' potential financial conflicts, including significant investments, consulting arrangements, employer affiliations and grants/contracts. Financial ties of potential reviewers to regulated entities (*e.g.*, businesses), other stakeholders, and regulatory agencies shall be scrutinized when the information being reviewed is likely to be relevant to regulatory policy. The inquiry into potential conflicts goes beyond financial investments and business relationships and includes work as an expert witness, consulting arrangements, honoraria and sources of grants and contracts. To evaluate any real or perceived conflicts of interest with potential reviewers and questions regarding the independence of reviewers, agencies are referred to federal ethics requirements, applicable standards issued by the Office of Government Ethics, and the prevailing practices of the National Academy of Sciences. Specifically, peer reviewers who are Federal employees (including special government employees) are subject to Federal requirements governing conflicts of interest. *See, e.g.*, 18 U.S.C. 208; 5 CFR part 2635 (2004). With respect to reviewers who are not Federal employees, agencies shall adopt or adapt the NAS policy for committee selection with respect to evaluating conflicts of interest.[26] Both the NAS and the Federal government recognize that under certain circumstances some conflict may be unavoidable in order to obtain the necessary expertise. *See, e.g.*, 18 U.S.C. 208(b)(3); 5 U.S.C. App. 15 (governing NAS committees). To improve the transparency of the process, when an agency determines that it is necessary to use a reviewer with a real or perceived conflict of interest, the agency should consider publicly disclosing those conflicts. In such situations, the agency shall inform potential reviewers of such disclosure at the time they are recruited.

Disclosure and Attribution: Anonymous Versus Identified

Peer reviewers must have a clear understanding of how their comments will be conveyed to the authors of the document and to the public. When peer review of government reports is considered, the case for transparency is stronger, particularly when the report addresses an issue with significant ramifications for the public and private sectors. The public may not have confidence in the peer review process when the names and affiliations of the peer reviewers are unknown. Without access to the comments of reviewers, the public is incapable of determining whether the government has seriously considered the comments of reviewers and made appropriate revisions. Disclosure of the slate of reviewers and the substance of their comments can strengthen public confidence in the peer review process. It is common at many journals and research funding agencies to disclose annually the slate of reviewers. Moreover, the National Academy of Sciences now discloses the names of its peer reviewers, without disclosing the substance of their comments. The science advisory committees to regulatory agencies typically disclose at least a summary of the comments of reviewers as well as their names and affiliations.

For agency-sponsored peer review conducted under Sections II and III, this Bulletin strikes a compromise by requiring disclosure of the identity of the reviewers, but not public attribution of specific comments to specific reviewers. The agency has considerable discretion in the implementation of this compromise (*e.g.*, summarizing the views of reviewers as a group or disclosing individual reviewer comments without attribution). Whatever approach is employed, the agency must inform reviewers in advance of how it intends to address this issue. Information about a reviewer retrieved from a record filed by the reviewer's name or other identifier may be disclosed only as permitted by the conditions of disclosure enumerated in the Privacy Act, 5 U.S.C. 552a as amended, and as interpreted in OMB implementing guidance, 40 FR 28,948 (July 9, 1975).

Public Participation

Public comments can be important in shaping expert deliberations. Agencies may decide that peer review should precede an opportunity for public comment to ensure that the public receives the most scientifically strong product (rather than one that may change substantially as a result of peer reviewer suggestions). However, there are situations in which public participation in peer review is an important aspect of obtaining a high-quality product through a credible process. Agencies, however, should avoid open-ended comment periods, which may delay completion of peer reviews and complicate the completion of the final work product.

Public participation can take a variety of forms, including opportunities to provide oral comments before a peer review panel or requests to provide written comments to the peer reviewers. Another option is for agencies to publish a "request for comment" or other notice in which they solicit public comment before a panel of peer reviewers performs its work.

Disposition of Reviewer Comments

A peer review is considered completed once the agency considers and addresses the reviewers' comments. All reviewer comments should be given consideration and be incorporated where relevant and valid. For instance, in the context of risk assessments, the National Academy of Sciences recommends that peer review include a written evaluation made available for public inspection.[27] In cases where there is a public panel, the agency should plan publication of the peer review report(s) and the agency's response to peer reviewer comments.

In addition, the credibility of the final scientific report is likely to be enhanced if the public understands how the agency addressed the specific concerns raised by the peer reviewers. Accordingly, agencies should consider preparing a written response to the peer review report explaining: The agency's agreement or disagreement, the actions the agency has undertaken or will undertake in response to the report, and (if applicable) the reasons the agency believes those actions satisfy any key

[24] American Society for Mechanical Engineers, *Assessment of Technologies Supported by the Office of Science and Technology, Department of Energy: Results of the Peer Review for Fiscal Year 2002*, ASME Technical Publishing, Danvers, MA, 2003.

[25] National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: *http://www.nationalacademies.org/coi/index.html.*

[26] Ibid.

[27] National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington, DC, 1983.

concerns or recommendations in the report.

Adequacy of Prior Peer Review

In light of the broad range of information covered by Section II, agencies are directed to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review.

Publication in a refereed scientific journal may mean that adequate peer review has been performed. However, the intensity of peer review is highly variable across journals. There will be cases in which an agency determines that a more rigorous or transparent review process is necessary. For instance, an agency may determine a particular journal review process did not address questions (*e.g.*, the extent of uncertainty inherent in a finding) that the agency determines should be addressed before disseminating that information. As such, prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary.

Section III: Peer Review of Highly Influential Scientific Assessments

Whereas Section II leaves most of the considerations regarding the form of the peer review to the agency's discretion, Section III requires a more rigorous form of peer review for highly influential scientific assessments. The requirements of Section II of this Bulletin apply to Section III, but Section III has some additional requirements, which are discussed below. In planning a peer review under Section III, agencies typically will have to devote greater resources and attention to the issues discussed in Section II, i.e., individual versus panel review; timing; scope of the review; selection of reviewers; disclosure and attribution; public participation; and disposition of reviewer comments.

A scientific assessment is considered "highly influential" if the agency or the OIRA Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest. One of the ways information can exert economic impact is through the costs or benefits of a regulation based on the disseminated information. The qualitative aspect of this definition may be most useful in cases where it is difficult for an agency to predict the potential economic effect of dissemination. In the context of this Bulletin, it may be either the approach used in the assessment or the interpretation of the information itself that is novel or precedent-setting. Peer review can be valuable in establishing the bounds of the scientific debate when methods or interpretations are a source of controversy among interested parties. If information is covered by Section III, an agency is required to adhere to the peer review procedures specified in Section III.

Section III(2) clarifies that the principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this Section are generally presumed not to require additional peer review. All other highly influential scientific assessments require a review that meets the requirements of Section III of this Bulletin.

With regard to the selection of reviewers, Section III(3)(a) emphasizes consideration of expertise and balance. As discussed in Section II, expertise refers to the required knowledge, experience and skills required to perform the review whereas balance refers to the need for diversity in scientific perspective and disciplines. We emphasize that the term "balance" here refers not to balancing of stakeholder or political interests but rather to a broad and diverse representation of respected perspectives and intellectual traditions within the scientific community, as discussed in the NAS policy on committee composition and balance.[28]

Section III(3)(b) instructs agencies to consider barring participation by scientists with a conflict of interest. The conflict of interest standards for Sections II and III of the Bulletin are identical. As discussed under Section II, those peer reviewers who are Federal employees, including Special Government Employees, are subject to applicable statutory and regulatory standards for Federal employees. For non-government employees, agencies shall adopt or adapt the NAS policy for committee member selection with respect to evaluating conflicts of interest.

Section III(3)(c) instructs agencies to ensure that reviewers are independent of the agency sponsoring the review. Scientists employed by the sponsoring agency are not permitted to serve as reviewers for highly influential scientific assessments. This does not preclude Special Government Employees, such as academics appointed to advisory committees, from serving as peer reviewers. The only exception to this ban would be the rare situation in which a scientist from a different agency of a Cabinet-level department than the agency that is disseminating the scientific assessment has expertise, experience and skills that are essential but cannot be obtained elsewhere. In evaluating the need for this exception, agencies shall use the NAS criteria for assessing the appropriateness of using employees of sponsors (*e.g.*, the government scientist must not have had any part in the development or prior review of the scientific information and must not hold a position of managerial or policy responsibility).

We also considered whether a reviewer can be independent of the agency if that reviewer receives a substantial amount of research funding from the agency sponsoring the review. Research grants that were awarded to the scientist based on investigator-initiated, competitive, peer-reviewed proposals do not generally raise issues of independence. However, significant consulting and contractual relationships with the agency may raise issues of independence or conflict, depending upon the situation.

Section III(3)(d) addresses concerns regarding repeated use of the same reviewer in multiple assessments. Such repeated use should be avoided unless a particular reviewer's expertise is essential. Agencies should rotate membership across the available pool of qualified reviewers. Similarly, when using standing panels of scientific advisors, it is suggested that the agency rotate membership among qualified scientists in order to obtain fresh perspectives and reinforce the reality and perception of independence from the agency.

Section III(4) requires agencies to provide reviewers with sufficient background information, including access to key studies, data and models, to perform their role as peer reviewers. In this respect, the peer review envisioned in Section III is more rigorous than some forms of journal peer review, where the reviewer is often not provided access to underlying data or models. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under Federal information quality laws.

[28] National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," May 2003: Available at: *http://www.nationalacademies.org/coi/index.html.*

Section III(5) addresses opportunity for public participation in peer review, and provides that the agency shall, wherever possible, provide for public participation. In some cases, an assessment may be so sensitive that it is critical that the agency's assessment achieve a high level of quality before it is publicized. In those situations, a rigorous yet confidential peer review process may be appropriate, prior to public release of the assessment. If an agency decides to make a draft assessment publicly available at the onset of a peer review process, the agency shall, whenever possible, provide a vehicle for the public to provide written comments, make an oral presentation before the peer reviewers, or both. When written public comments are received, the agency shall ensure that peer reviewers receive copies of comments that address significant scientific issues with ample time to consider them in their review. To avoid undue delay of agency activities, the agency shall specify time limits for public participation throughout the peer review process.

Section III(6) requires that agencies instruct reviewers to prepare a peer review report that describes the nature and scope of their review and their findings and conclusions. The report shall disclose the name of each peer reviewer and a brief description of his or her organizational affiliation, credentials and relevant experiences. The peer review report should either summarize the views of the group as a whole (including any dissenting views) or include a verbatim copy of the comments of the individual reviewers (with or without attribution of specific views to specific names). The agency shall also prepare a written response to the peer review report, indicating whether the agency agrees with the reviewers and what actions the agency has taken or plans to take to address the points made by reviewers. The agency is required to disseminate the peer review report and the agency's response to the report on the agency's Web site, including all the materials related to the peer review such as the charge statement, peer review report, and agency response to the review. If the scientific information is used to support a final rule then, where practicable, the peer review report shall be made available to the public with enough time for the public to consider the implications of the peer review report for the rule being considered.

Section III(7) authorizes but does not require an agency to commission an entity independent of the agency to select peer reviewers and/or manage the peer review process in accordance with this Bulletin. The entity may be a scientific or professional society, a firm specializing in peer review, or a non-profit organization with experience in peer review.

Section IV: Alternative Procedures

Peer review as described in this Bulletin is only one of many procedures that agencies can employ to ensure an appropriate degree of pre-dissemination quality of influential scientific information. For example, Congress has assigned the NAS a special role in advising the Federal government on scientific and technical issues. The procedures of the NAS are generally quite rigorous, and thus agencies should presume that major findings, conclusions, and recommendations of NAS reports meet the performance standards of this Bulletin.

As an alternative to complying with Sections II and III of this Bulletin, an agency may instead (1) rely on scientific information produced by the National Academy of Sciences, (2) commission the National Academy of Sciences to peer review an agency draft scientific information product, or (3) employ an alternative procedure or set of procedures, specifically approved by the OIRA Administrator in consultation with the Office of Science and Technology Policy (OSTP), that ensures that the scientific information product meets applicable information-quality standards.

An example of an alternative procedure is to commission a respected third party other than the NAS (*e.g.*, the Health Effects Institute or the National Commission on Radiation Protection and Measurement) to conduct an assessment or series of related assessments. Another example of an alternative set of procedures is the three-part process used by the National Institutes of Health (NIH) to generate scientific guidance. Under that process, a scientific proposal or white paper is generated by a working group composed of external, independent scientific experts; that paper is then forwarded to a separate external scientific council, which then makes recommendations to the agency. The agency, in turn, decides whether to adopt and/or modify the proposal. For large science agencies that have diverse research portfolios and do not have significant regulatory responsibilities, such as NIH, an acceptable alternative would be to allow scientists from one part of the agency (for example, an NIH institute) to participate in the review of documents prepared by another part of the agency, as long as the head of the agency confirms in writing that each of the reviewers meets the NAS criteria relating to the appropriateness of using employees of sponsors (*e.g.*, the government scientist must not have had any part in the development or prior review of the scientific information and must not hold a position of managerial or policy responsibility). The purpose of Section IV is to encourage these types of innovation in the methods used to ensure pre-dissemination quality control of influential scientific information.

The mere existence of a public comment process (*e.g.*, notice-and-comment procedures under the Administrative Procedure Act) does not constitute adequate peer review or an "alternative process," because it does not assure that qualified, impartial specialists in relevant fields have performed a critical evaluation of the agency's draft product.[29]

Section V: Peer Review Planning

Section V requires agencies to begin a systematic process of peer review planning for influential scientific information (including highly influential scientific assessments) that the agency plans to disseminate in the foreseeable future. A key feature of this planning process is a Web-accessible listing of forthcoming influential scientific disseminations (i.e., an agenda) that is regularly updated by the agency. By making these plans publicly available, agencies will be able to gauge the extent of public interest in the peer review process for influential scientific information, including highly influential scientific assessments. These Web-accessible agendas can also be used by the public to monitor agency compliance with this Bulletin.

Each entry on the agenda shall include a preliminary title of the planned report, a short paragraph describing the subject and purpose of the planned report, and an agency contact person. The agency shall provide its prediction regarding whether the dissemination will be "influential scientific information" or a "highly influential scientific assessment," as the designation can influence the type of peer review to be undertaken. The agency shall discuss the timing of the peer review, as well as the use of any deferrals. Agencies shall include entries in the agenda for influential scientific information, including highly influential scientific assessments, for which the Bulletin's requirements have

[29] William W. Lowrance, *Modern Science and Human Values*, Oxford University Press, New York, NY 1985: 86.

been deferred or waived. If the agency, in consultation with the OIRA Administrator, has determined that it is appropriate to use a Section IV "alternative procedure" for a specific dissemination, a description of that alternative procedure shall be included in the agenda.

Furthermore, for each entry on the agenda, the agency shall describe the peer review plan. Each peer review plan shall include: (i) A paragraph including the title, subject and purpose of the planned report, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan; (ii) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (iii) the timing of the review (including deferrals); (iv) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be exercised); (v) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; (vii) the anticipated number of reviewers (3 or fewer; 4–10; or more than 10); (viii) a succinct description of the primary disciplines or expertise needed in the review; (ix) whether reviewers will be selected by the agency or by a designated outside organization; and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers. The agency shall provide a link from the agenda to each document made public pursuant to this Bulletin. Agencies shall link their peer review agendas to the U.S. Government's official Web portal: firstgov at *http://www.FirstGov.gov.*

Agencies should update their peer review agendas at least every six months. However, in some cases—particularly for highly influential scientific assessments and other particularly important information—more frequent updates of existing entries on the agenda, or the addition of new entries to the agenda, may be warranted. When new entries are added to the agenda of forthcoming reports and other information, the public should be provided with sufficient time to comment on the agency's peer review plan for that report or product. Agencies shall consider public comments on the peer review plan. Agencies are encouraged to offer a listserve or similar mechanism for members of the public who would like to be notified by email each time an agency's peer review agenda has been updated.

The peer review planning requirements of this Bulletin are designed to be implemented in phases. Specifically, the planning requirements of the Bulletin will go into effect for documents subject to Section III of the Bulletin (highly influential scientific assessments) six months after publication. However, the planning requirements for documents subject to Section II of the Bulletin do not go into effect until one year after publication. It is expected that agency experience with the planning requirements of the Bulletin for the smaller scope of documents encompassed in Section III will be used to inform implementation of these planning requirements for the larger scope of documents covered under Section II.

Section VI: Annual Report

Each agency shall prepare an annual report that summarizes key decisions made pursuant to this Bulletin. In particular, each agency should provide to OIRA the following: (1) The number of peer reviews conducted subject to the Bulletin (i.e., for influential scientific information and highly influential scientific assessments); (2) the number of times alternative procedures were invoked; (3) the number of times waivers or deferrals were invoked (and in the case of deferrals, the length of time elapsed between the deferral and the peer review); (4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin, including determinations by the Secretary or Deputy Secretary pursuant to Section III(3)(c); (5) the number of peer review panels that were conducted in public and the number that allowed public comment; (6) the number of public comments provided on the agency's peer review plans; and (7) the number of peer reviewers that the agency used that were recommended by professional societies.

Section VII: Certification in the Administrative Record

If an agency relies on influential scientific information or a highly influential scientific assessment subject to the requirements of this Bulletin in support of a regulatory action, the agency shall include in the administrative record for that action a certification that explains how the agency has complied with the requirements of this Bulletin and the Information Quality Act. Relevant materials are to be placed in the administrative record.

Section VIII: Safeguards, Deferrals, and Waivers

Section VIII recognizes that individuals serving as peer reviewers have a privacy interest in information about themselves that the government maintains and retrieves by name or identifier from a system of records. To the extent information about a reviewer (name, credential, affiliation) will be disclosed along with his/her comments or analysis, the agency must comply with the requirements of the Privacy Act, 5 U.S.C. 552a, as amended, and OMB Circular A–130, Appendix I, 61 FR 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice. Furthermore, the peer review must be conducted in a manner that respects confidential business information as well as intellectual property.

Section VIII also allows for a deferral or waiver of the requirements of the Bulletin where necessary. Specifically, the agency head may waive or defer some or all of the peer review requirements of Sections II or III of this Bulletin if there is a compelling rationale for waiver or deferral. Waivers will seldom be warranted under this provision because the Bulletin already provides significant safety valves, such as: The exemptions provided in Section IX, including the exemption for time-sensitive health and safety information; the authorization for alternative procedures in Section IV; and the overall flexibility provided for peer reviews of influential scientific information under Section II. Nonetheless, we have included this waiver and deferral provision to ensure needed flexibility in unusual and compelling situations not otherwise covered by the exemptions to the Bulletin, such as situations where unavoidable legal deadlines prevent full compliance with the Bulletin before information is disseminated. Deadlines found in consent decrees agreed to by agencies after the Bulletin is issued will not ordinarily warrant waiver of the Bulletin's requirements because those deadlines should be negotiated to permit time for all required procedures, including peer review. In addition, when an agency is unavoidably up against a deadline, deferral of some or all requirements of the Bulletin (as opposed to outright waiver of all of them) is the most appropriate accommodation between the need to satisfy immovable deadlines and the need to undertake proper peer review. If the agency head defers any of the peer

review requirements prior to dissemination, peer review should be conducted as soon as practicable thereafter.

Section IX: Exemptions

There are a variety of situations where agencies need not conduct peer review under this Bulletin. These include, for example, disseminations of sensitive information related to certain national security, foreign affairs, or negotiations involving international treaties and trade where compliance with this Bulletin would interfere with the need for secrecy or promptness.

This Bulletin does not cover official disseminations that arise in adjudications and permit proceedings, unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel (i.e., a major change in accepted practice) or likely to have precedent-setting influence on future adjudications or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities as well as site-specific activities. The determination as to whether peer review is practical and appropriate is left to the discretion of the agency. While this Bulletin is not broadly applicable to adjudications, agencies are encouraged to hold peer reviews of scientific assessments supporting adjudications to the same technical standards as peer reviews covered by the Bulletin, including transparency and disclosure of the data and models underlying the assessments. Protections apply to confidential business information.

The Bulletin does not cover time-sensitive health and safety disseminations, for example, a dissemination based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began. For this purpose, "health" includes public health, or plant or animal infectious diseases.

This Bulletin covers original data and formal analytic models used by agencies in Regulatory Impact Analyses (RIAs). However, the RIA documents themselves are already reviewed through an interagency review process under E.O. 12866 that involves application of the principles and methods defined in OMB Circular A–4. In that respect, RIAs are excluded from coverage by this Bulletin, although agencies are encouraged to have RIAs reviewed by peers within the government for adequacy and completeness.

The Bulletin does not cover accounting, budget, actuarial, and financial information including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes.

Routine statistical information released by Federal statistical agencies (*e.g.*, periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (*e.g.*, unemployment and poverty rates) is excluded from this Bulletin.

The Bulletin does not cover information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.

If information is disseminated pursuant to an exemption to this Bulletin, subsequent disseminations are not automatically exempted. For example, if influential scientific information is first disseminated in the course of an exempt agency adjudication, but is later disseminated in the context of a non-exempt rulemaking, the subsequent dissemination will be subject to the requirements of this Bulletin even though the first dissemination was not.

Section X: OIRA and OSTP Responsibilities

OIRA, in consultation with OSTP, is responsible for overseeing agency implementation of this Bulletin. In order to foster learning about peer review practices across agencies, OIRA and OSTP shall form an interagency workgroup on peer review that meets regularly, discusses progress and challenges, and recommends improvements to peer review practices.

Section XI: Effective Date and Existing Law

The requirements of this Bulletin, with the exception of Section V, apply to information disseminated on or after six months after publication of this Bulletin. However, the Bulletin does not apply to information that is already being addressed by an agency-initiated peer review process (*e.g.*, a draft is already being reviewed by a formal scientific advisory committee established by the agency). An existing peer review mechanism mandated by law should be implemented by the agency in a manner as consistent as possible with the practices and procedures outlined in this Bulletin. The requirements of Section V apply to "highly influential scientific assessments," as designated in Section III of the Bulletin, within six months of publication of the final Bulletin. The requirements in Section V apply to documents subject to Section II of the Bulletin one year after publication of the final Bulletin.

Section XII: Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

Bulletin for Peer Review

I. Definitions

For purposes of this Bulletin—

1. The term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA);

2. The term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. 3502(1);

3. The term "dissemination" means agency initiated or sponsored distribution of information to the public (see 5 CFR 1320.3(d) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act or similar law. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. The term "dissemination" also excludes information distributed for peer review in compliance with this Bulletin, provided that the distributing agency includes a clear disclaimer on the information as follows: "This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by [the agency]. It does not represent and should not be construed to represent any agency determination or policy." For the purposes of this Bulletin, "dissemination" excludes research produced by government-funded scientists (*e.g.*, those supported extramurally or intramurally by Federal

agencies or those working in state or local governments with Federal support) if that information does not represent the views of an agency. To qualify for this exemption, the information should display a clear disclaimer that "the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency";

4. The term "Information Quality Act" means Section 515 of Public Law 106–554 (Pub. L. No. 106–554, § 515, 114 Stat. 2763, 2763A–153–154 (2000));

5. The term "scientific information" means factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a Web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes clear that what is being offered is someone's opinion rather than fact or the agency's views;

6. The term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions; and

7. The term "scientific assessment" means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

II. Peer Review of Influential Scientific Information

1. *In General:* To the extent permitted by law, each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate. Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the Federal laws governing information access and quality.

2. *Adequacy of Prior Peer Review:* For information subject to this section of the Bulletin, agencies need not have further peer review conducted on information that has already been subjected to adequate peer review. In determining whether prior peer review is adequate, agencies shall give due consideration to the novelty and complexity of the science to be reviewed, the importance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.

3. *Selection of Reviewers:* a. *Expertise and Balance:* Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. *Conflicts:* The agency—or the entity selecting the peer reviewers—shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable Federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating the potential for conflicts (*e.g.*, those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). For scientific information relevant to specific regulations, the agency shall examine a reviewer's financial ties to regulated entities (*e.g.*, businesses), other stakeholders, and the agency.

c. *Independence:* Peer reviewers shall not have participated in development of the work product. Agencies are encouraged to rotate membership on standing panels across the pool of qualified reviewers. Research grants that were awarded to scientists based on investigator-initiated, competitive, peer-reviewed proposals generally do not raise issues as to independence or conflicts.

4. *Choice of Peer Review Mechanism:* The choice of a peer review mechanism (for example, letter reviews or ad hoc panels) for influential scientific information shall be based on the novelty and complexity of the information to be reviewed, the importance of the information to decision making, the extent of prior peer review, and the expected benefits and costs of review, as well as the factors regarding transparency described in II(5).

5. *Transparency:* The agency—or entity managing the peer review—shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions. The peer review report shall either (a) include a verbatim copy of each reviewer's comments (either with or without specific attributions) or (b) represent the views of the group as a whole, including any disparate and dissenting views. The agency shall disclose the names of the reviewers and their organizational affiliations in the report. Reviewers shall be notified in advance regarding the extent of disclosure and attribution planned by the agency. The agency shall disseminate the final peer review report on the agency's Web site along with all materials related to the peer review (any charge statement, the peer review report, and any agency response). The peer review report shall be discussed in the preamble to any related rulemaking and included in the administrative record for any related agency action.

6. *Management of Peer Review Process and Reviewer Selection:* The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

III. Additional Peer Review Requirements for Highly Influential Scientific Assessments

1. *Applicability:* This section applies to influential scientific information that the agency or the Administrator determines to be a scientific assessment that:

(i) Could have a potential impact of more than $500 million in any year, or

(ii) Is novel, controversial, or precedent-setting or has significant interagency interest.

2. *In General:* To the extent permitted by law, each agency shall conduct peer reviews on all information subject to this Section. The peer reviews shall satisfy the requirements of Section II of this Bulletin, as well as the additional

requirements found in this Section. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this Section are generally presumed not to require additional peer review.

3. *Selection of Reviewers:* a. *Expertise and Balance:* Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. *Conflicts:* The agency—or the entity selecting the peer reviewers—shall (i) ensure that those reviewers serving as Federal employees (including special government employees) comply with applicable Federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences' policy for committee selection with respect to evaluating the potential for conflicts (*e.g.*, those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). For scientific assessments relevant to specific regulations, a reviewer's financial ties to regulated entities (*e.g.*, businesses), other stakeholders, and the agency shall be examined.

c. *Independence:* In addition to the requirements of Section II (3)(c), which shall apply to all reviews conducted under Section III, the agency—or entity selecting the reviewers—shall bar participation of scientists employed by the sponsoring agency unless the reviewer is employed only for the purpose of conducting the peer review (*i.e.*, special government employees). The only exception to this bar would be the rare case where the agency determines, using the criteria developed by NAS for evaluating use of "employees of sponsors," that a premier government scientist is (a) not in a position of management or policy responsibility and (b) possesses essential expertise that cannot be obtained elsewhere. Furthermore, to be eligible for this exception, the scientist must be employed by a different agency of the Cabinet-level department than the agency that is disseminating the scientific information. The agency's determination shall be documented in writing and approved, on a non-delegable basis, by the Secretary or Deputy Secretary of the department prior to the scientist's appointment.

d. *Rotation:* Agencies shall avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential and cannot be obtained elsewhere.

4. *Information Access:* The agency—or entity managing the peer review—shall provide the reviewers with sufficient information—including background information about key studies or models—to enable them to understand the data, analytic procedures, and assumptions used to support the key findings or conclusions of the draft assessment.

5. *Opportunity for Public Participation:* Whenever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues. To ensure that public participation does not unduly delay agency activities, the agency shall clearly specify time limits for public participation throughout the peer review process.

6. *Transparency:* In addition to the requirements specified in II(5), which shall apply to all reviews conducted under Section III, the peer review report shall include the charge to the reviewers and a short paragraph on both the credentials and relevant experiences of each peer reviewer. The agency shall prepare a written response to the peer review report explaining (a) the agency's agreement or disagreement with the views expressed in the report, (b) the actions the agency has undertaken or will undertake in response to the report, and (c) the reasons the agency believes those actions satisfy the key concerns stated in the report (if applicable). The agency shall disseminate its response to the peer review report on the agency's Web site with the related material specified in Section II(5).

7. *Management of Peer Review Process and Reviewer Selection:* The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

IV. Alternative Procedures

As an alternative to complying with Sections II and III of this Bulletin, an agency may instead: (i) Rely on the principal findings, conclusions and recommendations of a report produced by the National Academy of Sciences; (ii) commission the National Academy of Sciences to peer review an agency's draft scientific information; or (iii) employ an alternative scientific procedure or process, specifically approved by the Administrator in consultation with the Office of Science and Technology Policy (OSTP), that ensures the agency's scientific information satisfies applicable information quality standards. The alternative procedure(s) may be applied to a designated report or group of reports.

V. Peer Review Planning

1. *Peer Review Agenda:* Each agency shall post on its Web site, and update at least every six months, an agenda of peer review plans. The agenda shall describe all planned and ongoing influential scientific information subject to this Bulletin. The agency shall provide a link from the agenda to each document that has been made public pursuant to this Bulletin. Agencies are encouraged to offer a listserve or similar mechanism to alert interested members of the public when entries are added or updated.

2. *Peer Review Plans:* For each entry on the agenda the agency shall describe the peer review plan. Each peer review plan shall include: (i) A paragraph including the title, subject and purpose of the planned report, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan; (ii) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (iii) the timing of the review (including deferrals); (iv) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be employed); (v) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; (vii) the anticipated number of reviewers (3 or fewer; 4–10; or more than 10); (viii) a succinct description of the primary disciplines or expertise needed in the review; (ix) whether reviewers will be selected by the agency or by a

designated outside organization; and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers.

3. *Public Comment:* Agencies shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans. Agencies shall consider public comments on peer review plans.

VI. Annual Reports

Each agency shall provide to OIRA, by December 15 of each year, a summary of the peer reviews conducted by the agency during the fiscal year. The report should include the following: (1) The number of peer reviews conducted subject to the Bulletin (*i.e.*, for influential scientific information and highly influential scientific assessments); (2) the number of times alternative procedures were invoked; (3) the number of times waivers or deferrals were invoked (and in the case of deferrals, the length of time elapsed between the deferral and the peer review); (4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin, including determinations by the Secretary pursuant to Section III(3)(c); (5) the number of peer review panels that were conducted in public and the number that allowed public comment; (6) the number of public comments provided on the agency's peer review plans; and (7) the number of peer reviewers that the agency used that were recommended by professional societies.

VII. Certification in the Administrative Record

If an agency relies on influential scientific information or a highly influential scientific assessment subject to this Bulletin to support a regulatory action, it shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this Bulletin and the applicable information quality guidelines. Relevant materials shall be placed in the administrative record.

VIII. Safeguards, Deferrals, and Waivers

1. *Privacy:* To the extent information about a reviewer (name, credentials, affiliation) will be disclosed along with his/her comments or analysis, the agency shall comply with the requirements of the Privacy Act, 5 U.S.C. 522a as amended, and OMB Circular A–130, Appendix I, 61 FR 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice.

2. *Confidentiality:* Peer review shall be conducted in a manner that respects (i) confidential business information and (ii) intellectual property.

3. *Deferral and Waiver:* The agency head may waive or defer some or all of the peer review requirements of Sections II and III of this Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable.

IX. Exemptions

Agencies need not have peer review conducted on information that is:

1. Related to certain national security, foreign affairs, or negotiations involving international trade or treaties where compliance with this Bulletin would interfere with the need for secrecy or promptness;

2. Disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination), unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings;

3. A health or safety dissemination where the agency determines that the dissemination is time-sensitive (*e.g.*, findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began);

4. An agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866, except for underlying data and analytical models used;

5. Routine statistical information released by federal statistical agencies (*e.g.*, periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (*e.g.*, unemployment and poverty rates);

6. Accounting, budget, actuarial, and financial information, including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes; or

7. Information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.

X. Responsibilities of OIRA and OSTP

OIRA, in consultation with OSTP, shall be responsible for overseeing implementation of this Bulletin. An interagency group, chaired by OSTP and OIRA, shall meet periodically to foster better understanding about peer review practices and to assess progress in implementing this Bulletin.

XI. Effective Date and Existing Law

The requirements of this Bulletin, with the exception of those in Section V (Peer Review Planning), apply to information disseminated on or after six months following publication of this Bulletin, except that they do not apply to information for which an agency has already provided a draft report and an associated charge to peer reviewers. Any existing peer review mechanisms mandated by law shall be employed in a manner as consistent as possible with the practices and procedures laid out herein. The requirements in Section V apply to "highly influential scientific assessments," as designated in Section III of this Bulletin, within six months of publication of this Bulletin. The requirements in Section V apply to documents subject to Section II of this Bulletin one year after publication of this Bulletin.

XII. Judicial Review

This Bulletin is intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

John D. Graham,

Administrator, Office of Information and Regulatory Affairs.

[FR Doc. 05–769 Filed 1–13–05; 8:45 am]

BILLING CODE 3110–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Meeting; Board of Directors

TIME AND DATE: Thursday, January 27, 2005, 9:30 a.m. (open portion); 9:45 a.m. (closed portion).

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, NW., Washington, DC.

STATUS: Meeting open to the public from 9:30 a.m. to 9:45 a.m.; closed portion will commence at 9:45 a.m. (approx.).

MATTERS TO BE CONSIDERED:

1. President's Report.

2. Approval of November 10, 2004 Minutes (open portion).

EPA
United States
Environmental Protection
Agency

Science and Technology Policy Council

PEER REVIEW HANDBOOK

4th Edition

00326

EPA/100/B-15/001

U.S. Environmental Protection Agency

Peer Review Handbook

4th Edition

October 2015

Prepared for the U.S. Environmental Protection Agency
under the direction of the EPA Peer Review Advisory Group

Science and Technology Policy Council
U.S. Environmental Protection Agency
Washington, D.C. 20460

DISCLAIMER

This 4th edition of the *Peer Review Handbook* was developed by the U.S. Environmental Protection Agency (hereafter EPA or the Agency) to provide guidance to EPA staff and managers who are planning and conducting peer reviews. It is intended to improve the internal management of EPA peer review by providing recommended procedures and approaches for EPA staff and managers. This 4th edition is a guidance manual and not a rule or regulation. Some topics in the Handbook refer to laws or EPA policies. In such cases, this Handbook provides recommendations for how those provisions can be implemented. The *Peer Review Handbook* does not replace existing laws or regulations, does not change or substitute for any legal requirement, and is not legally enforceable. This 4th edition does not create or confer legal rights or impose any legally binding requirements on EPA or any party. The use of non-mandatory language such as "may," "can" or "should" in this *Peer Review Handbook* does not connote a requirement but does indicate EPA's strongly preferred approach to ensure the quality of peer reviews conducted or initiated by EPA. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

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Peer Review Advisory Group (PRAG): Link to the list of members (with their office/region affiliation): http://intranet.ord.epa.gov/about/organization/osa/peer-review-advisory-group.

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FOREWORD

Science is the foundation that supports all of our work at EPA. The quality and integrity of the science that underlies our regulations are vital to the credibility of EPA's decisions and, ultimately, the Agency's effectiveness in pursuing its mission to protect human health and the environment. One important element in ensuring that decisions are based on sound and defensible science is to have an open and transparent peer review process.

EPA has a long-standing history of peer review. The Agency has been a leader across the federal government in developing guidance and support for the peer review process. Even before issuing its Agency-wide Peer Review Policy in 1993, EPA was committed to peer review of its scientific and technical products. Over the years, EPA has repeatedly reaffirmed and updated both its Peer Review Policy and the processes for implementing peer review to ensure that EPA decisions rest on credible science and data.

The Agency's *Peer Review Handbook* was first released in 1998 and has been updated several times since. Each update has emphasized greater transparency and accountability for peer review. The last edition of the Handbook (2006) incorporated the provisions of the Office of Management and Budget's (OMB) *Final Information Quality Bulletin for Peer Review*. An EPA Addendum to the Handbook in 2009 provided guidance on preventing ethics concerns related to the appearance of a loss of impartiality for peer reviewers.

This newly revised 4th edition of the *Peer Review Handbook*, commissioned by the EPA Science and Technology Policy Council (STPC), supersedes all previous editions. Although the basic peer review procedures in the 2006 *Peer Review Handbook* remain current and our overall approach to peer review is not changing, this revision enhances and reinforces the practice of peer review at the Agency.

This *Peer Review Handbook* should be used as guidance by EPA staff and managers to ensure that the Agency's Peer Review Policy is implemented effectively and that the integrity of our peer review activities can be demonstrated transparently to the American public.

Thomas A. Burke, PhD, MPH
EPA Science Advisor

PREFACE

The first edition of the EPA *Peer Review Handbook* was issued in 1998 and was intended to serve as a single, centralized source of implementation guidance on peer review for EPA staff and managers. Subsequent revisions of the Handbook have added necessary clarifications, incorporated insights and experiences gained through its use, and integrated changes to reflect updated government-wide guidance or policy related to peer review. These revisions have increased the transparency and accountability of peer review and helped ensure that Agency decisions are based on sound and defensible science.

For the 4th edition, the EPA's STPC determined that revisions were needed to incorporate several recent EPA policy and process changes related to peer review. Although the 4th edition draws heavily from the 3rd edition, it has been reorganized to emphasize the elements and tools needed to implement a systematic peer review. It retains, however, the "question and answer" format throughout. New flowcharts and checklists have been added, and several substantial updates are included, such as the additional guidance on appearance of a loss of impartiality in external peer reviews, new information on organizational changes and oversight responsibilities, and changes related to the issuance of recent policies and procedures associated with the EPA's Information Quality Guidelines (IQG). The 4th edition also describes process changes for contractor-managed panel peer reviews of scientific and technical documents designated as Influential Scientific Information (ISI), including Highly Influential Scientific Assessments (HISAs), which are a subset of ISI. The process is intended to reduce the potential for organizational or personal conflict-of-interest (COI) concerns. Early public participation in the nomination and selection of peer reviewers and increased internal oversight are features of the process.

As in previous editions of the Handbook, not every peer review scenario can be anticipated or discussed. Through the use of examples, tools (e.g., flow diagrams, checklists) and process descriptions, however, this 4th edition illustrates practices from across the Agency that demonstrate effective implementation of peer review policy. The use of the recommended procedures and approaches in this Handbook should reinforce the open, transparent and objective peer review of Agency products.

ABBREVIATIONS AND ACRONYMS

AA	Assistant Administrator
ADP	Action Development Process
CASAC	Clean Air Scientific Advisory Committee
CBI	Confidential Business Information
CO	Contract(ing) Officer
COI	Conflict of Interest
COR	Contracting Officer's Representative
DA	Deputy Administrator
DAEO	Designated Agency Ethics Official
DEO	Deputy Ethics Official
DFO	Designated Federal Officer
DM	Decision Maker
DQA	Director of Quality Assurance
EIS	Environmental Impact Statement
EPA	U.S. Environmental Protection Agency
EPAAG	EPA Acquisition Guide
FAC	Federal Advisory Committee
FACA	Federal Advisory Committee Act
FAR	Federal Acquisition Regulations
FOIA	Freedom of Information Act
FTE	Full-Time Equivalent
GSAPR	Gratuitous Services Agreement for Peer Review
HISA	Highly Influential Scientific Assessment
IGA	Inherently Governmental Activity
IQG	Information Quality Guidelines
IRIS	Integrated Risk Information System
ISI	Influential Scientific Information
NAS	National Academy of Sciences
NCEA	National Center for Environmental Assessment
NEPA	National Environmental Policy Act
NRC	National Research Council
NTTAA	National Technology Transfer and Advancement Act of 1995
OGC	Office of General Counsel
OGE	U.S. Office of Government Ethics
OMB	Office of Management and Budget
ORC	Office of Regional Counsel
ORD	Office of Research and Development
OSA	Office of the Science Advisor
PI	Principal Investigator
PL	Project Leader
PM	Project Manager
PRAG	Peer Review Advisory Group
PRC	Peer Review Coordinator
PRL	Peer Review Leader
QA	Quality Assurance
QAM	Quality Assurance Manager
RA	Regional Administrator

RGE	Regular Government Employee
ROD	Record of Decision
SAB	Science Advisory Board
SAP	Scientific Advisory Panel
SGE	Special Government Employee
SI	Science Inventory
SOW	Statement of Work
STPC	Science and Technology Policy Council

ROADMAP TO PEER REVIEW AT EPA

ROADMAP TO PEER REVIEW AT EPA

R.1. Overview

The goal of this roadmap is to assist the user in understanding how to apply the material in the Handbook and determining where important decisions should be made and documented. Figure 1 summarizes the Agency's overall peer review process, whereas Figures 2 and 3 provide additional details of the key steps, decisions and milestones. This roadmap is not meant to be a stand-alone document but is to be used as a quick reference to users already familiar with the systematic process of planning, conducting and completing peer reviews. Roadmap users will find flowcharts summarizing major decision points in the process and times where documentation is needed, with references to specific sections in the Handbook containing more detailed information. Although the roadmap assumes familiarity with general Agency terminology, Section 1.2 of the Handbook discusses key terms associated with this guidance.

This roadmap also includes example tools for (1) documenting peer review decisions; (2) developing regulatory action; and (3) planning, conducting and completing the peer review. Because these tools vary depending on both the intended use of the work product and the decisions to be made, more than one tool generally is needed.

R.2. Relationship between the Roadmap and Chapters 1 Through 7

The roadmap figures show the peer review process from start to finish. The Handbook Chapters 1 through 7 have been organized to describe essential elements and concepts (the "what") needed for successful implementation of the peer review process. General concepts included are:

- providing terms and context (see Chapter 1);
- identifying relevant peer review roles, responsibilities and resource considerations of Agency personnel and organizations (see Chapter 2);
- categorizing work products (see Chapter 3);
- determining the appropriate peer review approach (see Chapter 4);
- selecting reviewers and considering associated ethics issues such as potential conflicts of interest (COIs) or an appearance of a loss of impartiality (see Chapter 5);
- conducting and completing the review, including developing the peer review charge (see Chapter 6); and
- ensuring transparency during various steps in the peer review process (see Chapter 7).

For some, the process may be described more effectively visually, using diagrams or graphics to make relationships more apparent and provide easy navigation through the entire process. Figures 1 through 3 are the main processes described in this Handbook, provided in graphic form.

Figure 1, the diagram of the peer review process, illustrates the Agency's overall peer review process for scientific or technical (including economic and social science) work products. The Agency process emphasizes early categorization of the work product—preferably at the conceptual stage—into one of three categories: Influential Scientific Information (ISI); Highly Influential Scientific Assessment (HISA), which is a subset of ISI; or other. The ISI and HISA categories have been identified and defined by the Office of Management and Budget (OMB) in its *Final Information Quality Bulletin for Peer Review* (OMB Peer Review Bulletin) (Appendix B). Management approval and documentation of key decisions throughout the peer review process are emphasized. The EPA also demonstrates its commitment to transparency in the peer review process by providing opportunities for public participation.

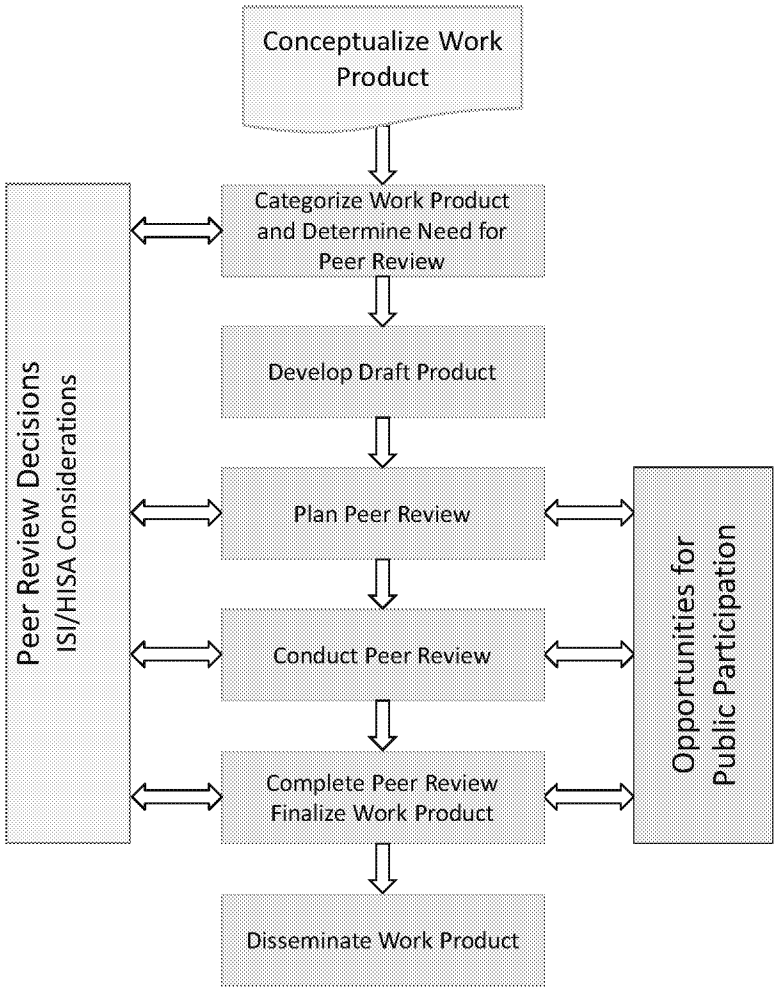


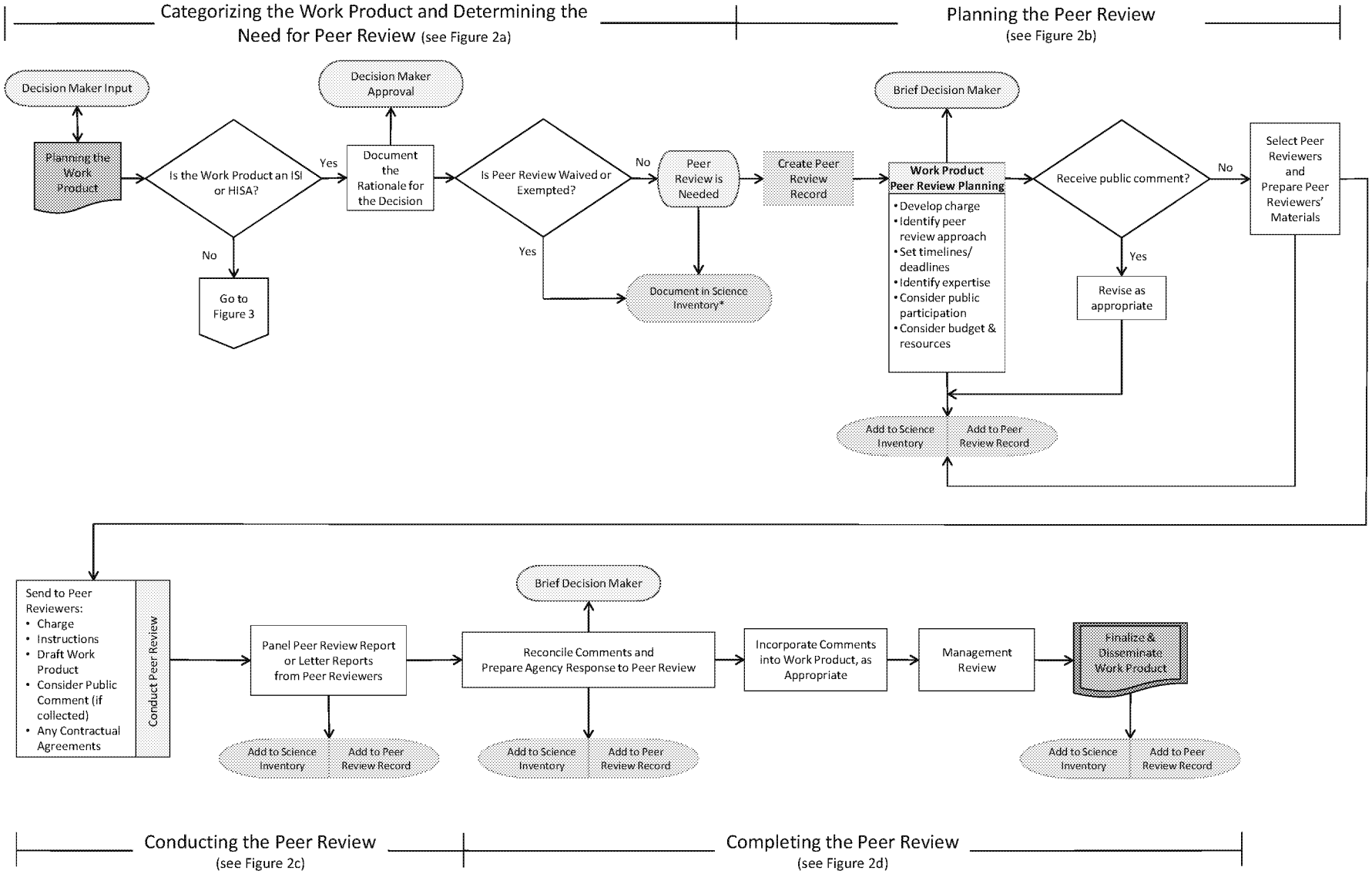
Figure 1. The Peer Review Process

Figure 2, the peer review flowchart for influential work products, illustrates details associated with the general process. Each of the four phases in this flowchart is presented subsequently in Figures 2a through 2d and references to relevant Handbook sections are provided. The figures also include steps at which the Decision Maker (DM) should be involved, and points at which the peer review record, as well as the EPA's searchable database for influential products, the Science Inventory (SI),[1] should be updated. Although updating the SI provides public access to the information about the peer review, the figures indicate various points in the peer review process where the public may also be provided opportunities to comment on materials in the SI.

Figure 3 illustrates the comparable flow for scientific or technical work products not categorized as ISI or a HISA. It includes a specific process for work products that will be submitted to peer-reviewed journals; in that case, work products are subject to management review (following the procedures of the program or regional office) prior to submission to a journal, and authors work with the journal editors/reviewers to resolve any comments. For more information on peer review of work products not categorized as ISI or a HISA, see Sections 3.2.5 and 3.2.6.

[1] EPA. 2015. *EPA Science Inventory.* http://cfpub.epa.gov/si/.

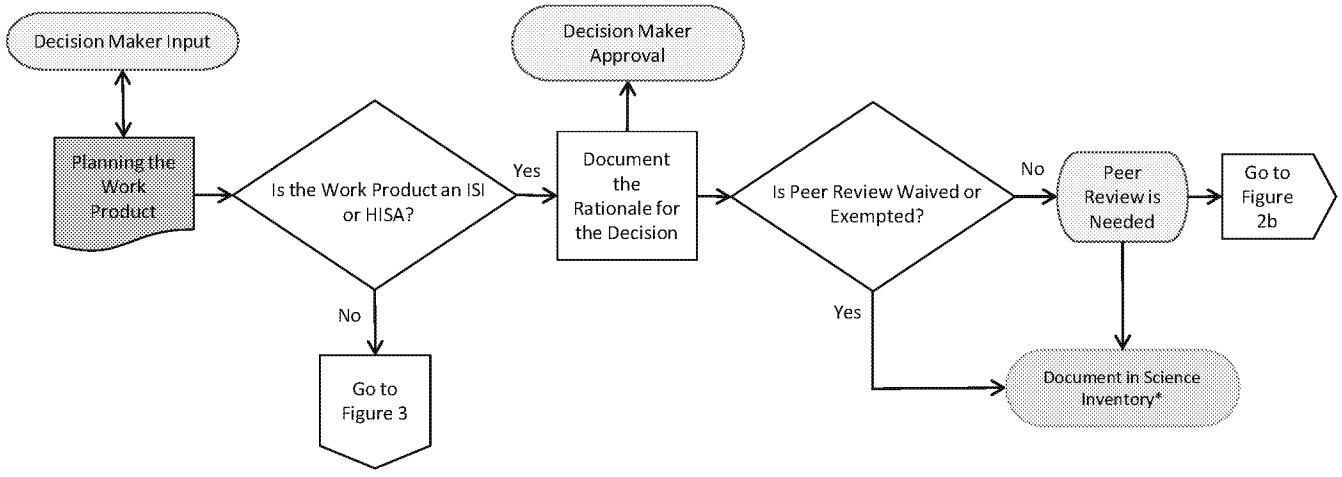
It should be noted that the peer review flow charts show the general steps that are followed for the peer review of work products at EPA. The specific steps taken by individual EPA offices will depend on many factors, including the type of work product, timeframe available for peer review and resource considerations. It should be noted that the term "EPA offices" in this Handbook refers to all headquarters, regional and program offices.



*Agency's Peer Review Agenda is created from information entered in the Science Inventory

Figure 2. Detailed Peer Review Flowchart for Influential Work Products (Including HISAs)*

* For work products categorized as "other," see Figure 3.



*Agency's Peer Review Agenda is created from information entered in the Science Inventory

Figure 2a. Categorizing the Work Product and Determining the Need for Peer Review

1. Determine if the work product:
- Is a scientific, engineering, economic, social science or statistical document (§ 3.1.1, 3.1.3)
- Is ISI/HISA (§§ 3.2.1, 3.2.3, 3.2.4)
- Other work product (see Figure 3)

2. Obtain categorization of work product from the DM:
- Document decision and rationale for decision
- Continue with peer review unless determined not to be needed

3. Peer review typically not needed if:
- ISI/HISA consists only of science previously peer reviewed and the previous peer review is deemed adequate under the Agency's policy (§ 3.3.2)
- ISI/HISA consists only of principal findings, conclusions and recommendations from National Academy of Sciences (NAS) official reports (Appendix B, Section III.2)
- Work product meets criteria for exemption (§§ 3.3.1, 3.3.2)
- Work product receives waiver (§ 3.3.3)
- Peer review otherwise determined not to be warranted

4. Add document with waiver/exemption to the SI[2]

[2] EPA. 2015. *Peer Review Agenda.* http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

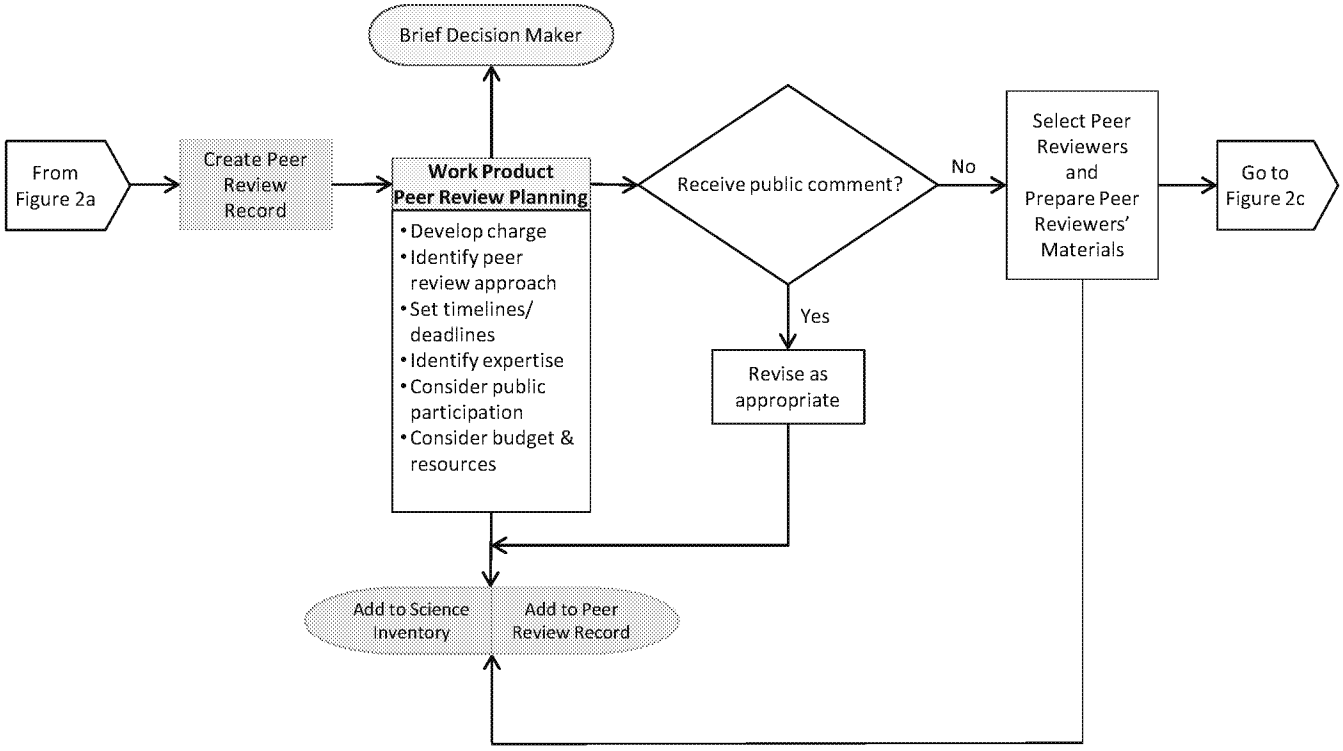


Figure 2b. Planning the Peer Review for Influential Scientific Information (Including HISAs)

1. If a work product is subject to peer review:
- Identify key staff (§ 2.3)
- Create a peer review record (§ 6.5)
- Identify criteria/basis for the charge (§ 6.2)
- Consider options for public participation (§ 7.2)

2. Develop the draft charge (§ 6.2):
- Determine which key issues to address
- Add to the SI and peer review record

3. Ensure adequate resources for the peer review (§ 1.2.5)

4. Identify a peer review approach (§ 4.2):
- Internal (§ 4.2.2), external (§ 4.2.3) or both, as appropriate
- Letter review (§ 4.4):
  - Managed by Agency or contractor (§ 4.6)
- Panel review (§ 4.5):
  - Managed by contractor or federal advisory committee (FAC) (§§ 4.6, 4.7)
  - One-time or multiple meetings (§§ 1.2.3, 4.2.1)
- Add to the SI and peer review record

5. Set timelines/deadlines:
- When will the review be started?
- What are the intermediate checkpoints?
- What is the deadline for completion?
- Add to the SI and peer review record

6. Identify expertise (§ 5):
- Determine the expertise needed (§§ 5.2.1, 5.2.4)
- Determine sources of peer reviewers (§ 5.2.2)
- Consider asking the public to nominate peer reviewers (§ 5.2.2)
- Consider and address the balance of the panel (§ 5.2.4)
- Consider COIs (§§ 4.6.4, 5.3)
- Particularly for a HISA, evaluate rotation (§ 5.2.8)
- If a contractor-managed panel peer review, note special considerations (§ 4.6.4)
- Formalize arrangement with peer reviewers
- Add to the SI and peer review record

7. Determine whether, on what and when public may provide comment (e.g., work product, charge, peer reviewers) (§ 7.2):
- Revise peer review plan accordingly
- Document in the SI and peer review record
- If a HISA, include a public comment process as part of the peer review whenever feasible and appropriate

8. Prepare materials for the peer review (§ 6.2.5):
- Obtain materials from the Project Manager
- Prepare instructions for peer reviewer (§ 6.2.5)
- Include a copy of materials in the peer review record (§ 6.5.2)

Note: Some of these steps may occur concurrently.

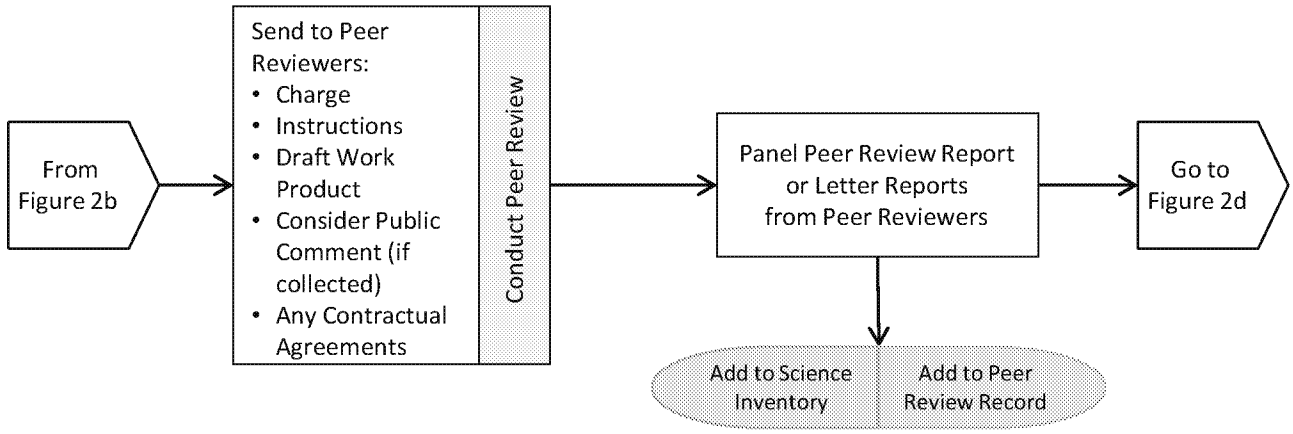


Figure 2c. Conducting the Peer Review of Influential Scientific Information (Including HISAs)

1. Provide materials to the peer reviewers (§ 6.2.5):
- Charge
- Instructions
- Draft work product
- Public comments if plan provided for public comment on work product
- Any contractual agreements associated with the review
- Particularly for HISAs, supporting materials for key decisions and findings

2. Conduct the peer review:
- Particularly if a HISA, public may present comments to peer reviewers at a panel meeting (should be part of peer review plan)

3. Ask reviewers to prepare peer review comments (§ 6.2.5)

4. Prepare Peer Review Report (collective comments from peer reviewers) (§ 6.2.5)
- If conducted by a panel, receive panel peer review report
- If conducted by letter, receive individual letter reviews and prepare consolidated peer review report

5. Add peer review report to the SI and peer review record

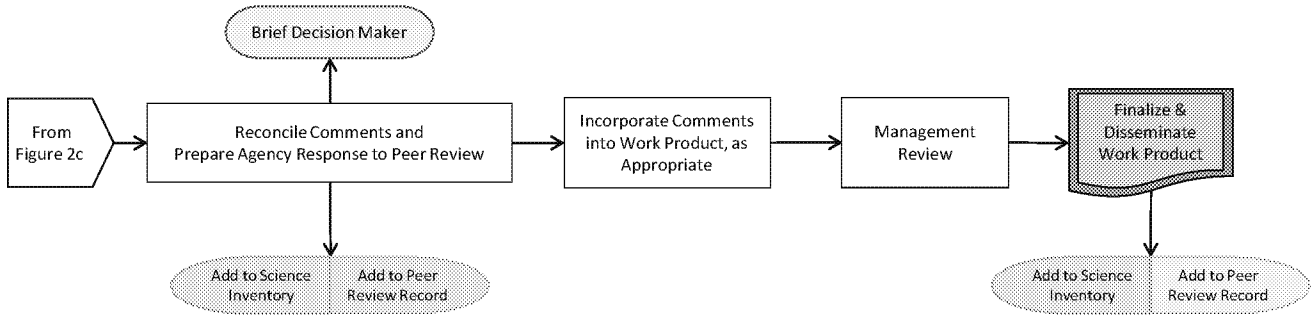


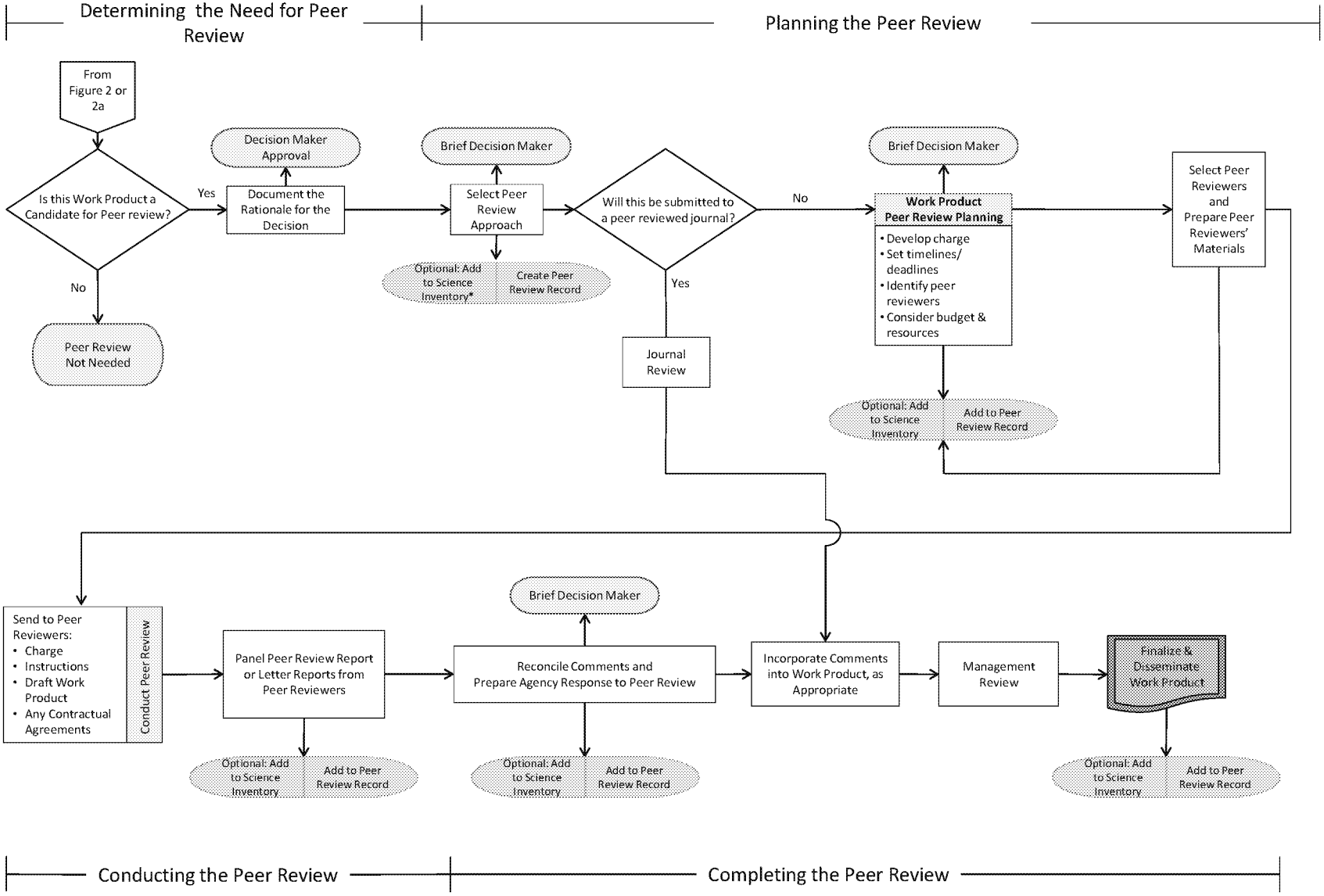
Figure 2d. Completing the Peer Review of Influential Scientific Information (Including HISAs)

1. Evaluate comments from peer reviewers:
- Consider comments
- Obtain clarification, if needed
- Include comments in peer review record

2. Brief the DM on proposed reconciliation of comments

3. Reconcile comments:
- Revise the work product by incorporating comments, as appropriate
- For a HISA, prepare a written Agency response and document why any comments were not used
- Include documentation in peer review record

4. Finalize work product:
- Include in peer review record
- Post peer review report and related materials (e.g., charge, Agency response) on the Internet through the SI:
  - For an ISI, post written Agency response to the peer review report, if prepared
  - For a HISA, post written Agency response to the peer review report
- For all ISI/HISAs that support rulemaking:
  - Include peer review discussion and certification in preamble of the rule



*Although other Work Products (non-Influential) may be added to the Science Inventory, they will not be on the EPA Peer Review Agenda

Figure 3. Detailed Flowchart for Other Work Products

R.3. Organizing the Peer Review Process

R.3.1. Planning the Peer Review

Planning a peer review is a critical first step to ensuring a successful peer review of a work product. The initial step is to determine whether the work product (either at the conceptual stage or while under development) should be peer reviewed. Once it has been determined that a peer review will be conducted, the DM and Peer Review Leader (PRL) need to plan an appropriate review. This includes:

- categorizing the work product and documenting the decision for influential work products;
- determining resources (budget and personnel);
- scheduling for completion of the peer review;
- creating the peer review record;
- making decisions about an appropriate peer review approach, which considers the forum (i.e., internal and/or external), type (i.e., letter or panel) and mechanism for conducting the review (i.e., Agency-managed, contractor-managed, Federal Advisory Committee [FAC], National Academy of Sciences [NAS]);
- planning for opportunities for public participation;
- developing the charge;
- selecting peer reviewers; and
- preparing materials for the reviewers.

Conceptualizing the Peer Review, which includes defining roles, responsibilities and resources, should take place at the very earliest stages of a product's development. Resources, including personnel, time and funding, should be considered. Based on individual EPA office procedures, other considerations might include the need for briefings, quality assurance (QA) components and reviews and pre-dissemination review planning and approvals.

Categorizing the Work Product (Figure 2a) is based on objective criteria associated with whether the work product is considered influential (i.e., is categorized as ISI), and if influential, whether it is a HISA.

Planning the Peer Review for Influential Scientific Information (Including HISAs) (Figure 2b) takes into account the work product categorization in determining the forum, type and mechanism of peer review. Evaluation and selection of peer reviewers are also documented in the plan, as well as decisions about public participation, preparation of the charge, instructions to reviewers and other information that may be useful to reviewers. For HISAs, in particular, it is important to include sufficient information, including background information about key studies or models, to enable reviewers to understand how significant findings or conclusions in the draft assessment were made.

The charge should be drafted before selection of the peer reviewers to ensure that they have the appropriate expertise to address the questions raised. Developing and maintaining a peer review record should begin at the planning stage of the peer review process (see Section 6.5.3).

R.3.2. Conducting the Peer Review

The success and usefulness of any peer review depends on the quality of the draft work product submitted for peer review, the care given to the statement of the issues or "charge," the match between the peer review draft product and the form of peer review, the match between the peer review draft product and the scientific/technical expertise of the reviewers, and Agency use of peer review comments in the final product. In conducting a peer review, each of the foregoing elements requires serious attention.

Figure 2c shows the order of activities for conducting a peer review of a work product categorized as ISI or a HISA. The peer reviewers are expected to prepare and submit peer review reports at the conclusion of their review. For letter reviews, individual reports are submitted; a single report generally is expected from a peer review panel.

R.3.3. Completing the Peer Review and Finalizing the Work Product

Conducting the peer review of the work product is not the final stage of the peer review process. Rather, the peer review process closes with the following major activities: evaluating peer review comments and recommendations, using the peer review comments for completing the final document, completing the peer review record, and including relevant information in the SI (Figure 2d). The final product represents the true end of the peer review process.

R.3.4. Tools for Managing the Peer Review Process

The following Exhibits may be used by EPA offices to plan, track and document decisions associated with peer review. Note that more than one of the following may be needed for a given draft work product:

- The *Regulatory Action Development Checklist for Workgroups* (Exhibit 1) is an aid for those involved in the development of regulatory actions.
- The list of *Recommended Steps for Planning, Conducting and Completing a Peer Review* (Exhibit 2) is to assist the Project Manager (PM) and PRL in tracking the overall peer review process.
- The *Example EPA Peer Review Decision Summary Documentation* (Exhibit 3) is for the DM, Peer Review Coordinator (PRC) and PRL to document decisions, including the work product categorization, mechanism of peer review and public participation.

Tools and products to enhance the transparency and reporting of peer reviews are summarized in Table 1.

Exhibit 1. Regulatory Action Development Checklist for Workgroups

This checklist will help workgroups plan for peer review in the larger context of regulatory development. Each numbered section corresponds to a time period in the regulatory development process.

1. **Peer Review Prior to Proposal**

   Tier 1 or Tier 2 Rule*
   - __ Is the peer review schedule incorporated into the analytic blueprint?
   - __ Does this rule rely upon influential scientific information (ISI/HISA)?
   - __ Will the work product be reviewed using external peer review?

   Tier 3 Rule
   - __ Is the peer review schedule incorporated into the plans for producing the action?
   - __ Does this rule rely upon ISI or a HISA?
   - __ If an internal mechanism will be used for peer review, is it acceptable according to the *Peer Review Handbook*?

2. **Sending a Proposed Rule Forward for the Administrator's Signature**
   - __ Has peer review been completed?
   - __ Does the action memorandum indicate whether the rule relies upon ISI or a HISA?
   - __ If the proposed rule relies on ISI or a HISA, is there a discussion of the peer review in the preamble of the rule?

3. **Before the Proposed Rule Publishes**
   - __ Were the peer review report and any relevant materials included in the docket for this rulemaking?

4. **Peer Review Prior to Finalization**
   - __ Is a new peer review plan necessary as a result of new regulatory options?

5. **Sending a Final Rule Forward for the Administrator's Signature**
   - __ Has any new peer review of the work product been completed?
   - __ Does the action memorandum indicate whether the rule relies on ISI or a HISA?
   - __ If the final rule relies on ISI or a HISA, is there a discussion of the peer review in the preamble of the rule?

6. **Before the Final Rule Publishes**
   - __ Were the peer review report and any relevant materials included in the docket for this rulemaking?

Note: For ISI and HISAs, the administrative record for the action should include a certification explaining that the action is consistent with provisions of the Office of Management and Budget (OMB) Peer Review Bulletin (see Appendix C).

* For further information on tiering and criteria used to determine the appropriate tier for an action, see http://intranet.epa.gov/actiondp/adp-milestones/tiering.htm .

Exhibit 2. Recommended Steps for Planning, Conducting and Completing a Peer Review

Recommended Steps	Comments
I. Categorize the work product and document your rationale (requires Decision Maker [DM] approval) (see *Example EPA Peer Review Decision Summary Documentation* form and Chapter 3) __ Influential scientific information (ISI) __ Highly influential scientific assessment (HISA) __ Other	
II. Plan the peer review and brief the DM (Chapters 4 and 5) __ Begin creating a peer review record __ Select the peer review approach • Internal, external or both • Letter or panel • EPA- or contractor-managed __ Set timelines/deadlines __ Consider budget and resources __ Develop charge questions __ Identify areas of expertise needed __ Consider public participation, stakeholder involvement __ Identify and evaluate potential peer reviewers (expertise and ethics issues) __ For HISAs and ISI, create public peer review plan and add other relevant information in the EPA Science Inventory * (see Chapter 7) __ Formalize arrangements with the selected peer reviewers	
III. Conduct the peer review (Chapter 6) __ Send peer review materials (e.g., charge and instructions, draft work product and supporting materials, contractual agreements, public comments) to peer reviewers __ Convene panel or conduct letter review __ Obtain reviewers' comments (peer review report)	
IV. Complete the peer review and brief the DM (Chapters 6 and 7) __ Reconcile reviewers' comments and document how comments were addressed __ Finalize work product __ Update peer review record __ For HISAs and ISI, post the peer review report, any Agency response (necessary for a HISA), and the final work product	

* EPA. Peer Review Agenda. http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

Exhibit 3. Example EPA Peer Review Decision Summary Documentation

1) WORK PRODUCT TITLE:

_____

2) WORK PRODUCT DESCRIPTION:

_____

3) Assistant Administrator (AA)-ship or Region and Originating Office/Division:

_____

4) Decision/Rule/Regulation/Action/Activity That the Work Product Supports:_____

5) Categorization of Work Product (see page 2 of this exhibit for explanation):

__ Influential Scientific Information (ISI)
__ Highly Influential Scientific Assessment (HISA)
__ Other Scientific or Technical Work Product

6) Rationale for Work Product Categorization and if Peer Review is needed:_____

7) Peer Review Mechanism(s) to Be Used, If Applicable (check all that apply):
(If the work product is designated as ISI or a HISA, conduct peer review [unless exempted or deferred]. For other scientific or technical work products, peer review should be conducted if the Decision Maker [DM] determines that it is appropriate. Evaluate and allot sufficient resources, including funds, time and personnel.)

__ Peer Review Not Necessary (provide rationale)
__ Internal
__ External: Submit to Peer-Reviewed Journal
__ External: Letter Reviews
__ External: Contractor-Managed Panel
__ External: Federal Advisory Committee (FAC) (e.g., Science Advisory Board [SAB])
__ External: Other Panels (e.g., National Academy of Sciences [NAS])

8) Opportunities for Public Participation (check all that apply):

__ Comment on Charge
__ Nominate Potential Peer Reviewers
__ Comment on Potential Peer Reviewers
__ Comment on Draft Work Product
__ Comment on Peer Review Mechanism
__ Oral Presentation to Reviewers

Documentation/Approval of Decision for an ISI or HISA Work Product

Peer Review Leader (Recommendation) _____ Date _____
Peer Review Coordinator (Concurrence) _____ Date _____
Decision Maker (Approval) _____ Date _____

The DM must approve the categorization decision for work products designated as ISI or HISA. Work products designated as ISI or HISA should be peer reviewed; for HISA, external peer review is the approach of choice. For work products not designated as ISI or a HISA, peer review should be conducted if the DM determines it is appropriate.

If the ISI/HISA work product is exempted or deferred from peer review, state the reason(s) why:

Note: Exemption or deferral from peer review of an ISI or HISA requires Administrator approval.

Exhibit 3. Example EPA Peer Review Decision Summary Documentation: Explanation

Yes/ No	Item/Instructions	Handbook Section
Designate the Work Product Category*— DM and Peer Review Coordinator (PRC)		
	Is Work Product Scientific or Technical (includes economic and social science work products)?	3.1.1
If scientific or technical, which designation does the work product best fit:		
	ISI:† Will have or does have a clear and substantial impact on important public policies or private sector decisions. Decision Makers should consider the following factors when determining whether a product is likely to be influential: • Establishes a significant precedent, model or methodology. • Is likely to have an annual effect on the economy of $100 million or more. • Is likely to adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or state, tribal or local governments or communities. • Addresses significant controversial issues. • Focuses on significant emerging issues. • Has significant cross-Agency/interagency implications. • Involves a significant investment of Agency resources. • Considers an innovative approach for a previously defined problem/process/methodology. • Satisfies a statutory or other legal mandate for peer review.	3.2.1
	HISA: A scientific assessment (i.e., an evaluation of a body of scientific/technical knowledge that typically synthesizes multiple inputs, data, models and assumptions and/or applies best professional judgment to bridge uncertainties in available information) that meets the following: • In addition to meeting the criteria for ISI, could have a potential impact of more than $500 million in any year; or • Is novel, controversial or precedent-setting or has significant interagency interest.	3.2.3
	Other (includes journal articles): • Define in comments.	3.2.5

* Designation of a work product's category could change during the course of development. Any changes in designation also should be documented and approved (see Section 3.2.7).

† For examples of Agency work products designated as ISI and HISAs, see the Peer Review Agenda website (http://cfpub.epa.gov/si/si_public_pr_agenda.cfm).

Table 1. Agency Tools and Products for Peer Review Transparency and Reporting

Tool (T)/Product (P)	Description	Handbook Section
(T) Roadmap Flowcharts	Graphically describe the Agency's peer review process.	Roadmap
(T) Example Decision Summary Documentation	Individual product documentation is used in each EPA office to start a record of management decision and approval to categorize a product and the type of peer review it will undergo. This document is used at the EPA office level.	Roadmap Exhibit 2
(T) Conducting a Peer Review	A planning and implementation tool for anyone managing the peer review process of a work product.	Roadmap Exhibit 1
(P) Public Peer Review Plan (automatically generated in the SI when information on ISI or a HISA is entered). The SI is a tool to help generate the public peer review plan.	Begin a systematic process of peer review planning for ISI and HISAs that an Agency plans to disseminate in the foreseeable future. Each peer review plan includes: • A paragraph including the title, subject and purpose of the planned report, as well as an Agency contact to whom inquiries may be directed to learn the specifics of the plan. • Whether the dissemination is likely to be ISI or a HISA. • The timing of the review (including deferrals). • Whether the review is conducted through a panel or individual letters (or whether an alternative procedure is exercised). • Whether there are opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities are provided. • Whether the Agency provides significant and relevant public comments to the peer reviewers before they conduct their review. • The anticipated number of reviewers (3 or fewer, 4–10 or more than 10). • A succinct description of the primary disciplines or expertise needed in the review. • Whether reviewers are selected by the Agency or by a designated outside organization. • Whether the public, including scientific or professional societies, are asked to nominate potential peer reviewers.	7.3.4
(P) Peer Review Charge	As part of each peer review, the PRL formulates a clear, focused charge that identifies the technical and scientific issues on which the Agency would like feedback and invites suggestions for improving the document as a whole. This request signals the Agency's receptivity to expert recommendations. The charge to peer reviewers usually makes two general requests. First, it focuses the review by presenting specific questions and concerns surrounding such issues as the comprehensiveness of the literature reviewed, the soundness of the method used, the scientific support for the assumptions employed, and the sensitivity analysis (i.e., the sensitivity of the results to alternative assumptions). Secondly, it invites general comments on the work product as a whole.	6.2
(P) The Peer Review Report(collective comments from peer reviewers)	The collective comments on the scientific or technical work product undergoing peer review provided by the peer reviewers in response to the peer review charge is called the Peer Review Report. The EPA makes the reports for ISI and HISAs available on the SI website, which links directly to the Peer Review Agenda entry for that item.	6.2.5

Table 1. Agency Tools and Products for Peer Review Transparency and Reporting

Tool (T)/Product (P)	Description	Handbook Section
(P) Agency's Response to Peer Review Report	The PRL should evaluate and analyze all peer review comments and recommendations carefully. The peer review of a work product is not complete until the peer review comments are incorporated into the final version or reasons are stated why such comments are not incorporated. The peer review record is complete only when it contains a copy of the final work product (when there is one) that addresses the peer review comments and a copy of the response-to-comments document. The PRL should brief the DM on how to address the peer review comments. Per the OMB Peer Review Bulletin, the Agency's response to the peer review report for HISAs should be posted on the SI.	6.3
(P) Peer Review Record	The peer review record is the formal record (file) of decision on the conduct of the peer review, including the type of peer review performed and an explanation of how the peer review comments are addressed. It includes sufficient documentation for an uninvolved individual to understand what happened and why. The peer review record is separate from the entry in the SI. Although some information from the peer review record appears in the SI, the paper peer review record is the official record of the peer review. The PRL (with the Project Manager [PM], if there is one) creates a separate, clearly marked peer review file within the overall file for development of the work. Once the peer review is completed, it is the responsibility of the PRL to ensure that the peer review record is filed and maintained in accordance with the organization's document retention procedures.	6.5
(T) Science Inventory	The SI (www.epa.gov/si) is a searchable database that contains information on EPA publications and presentations. The SI is used to track the Agency's work products that are categorized as ISI and HISAs, including their status and peer review plans. EPA offices are expected to keep this information current by updating SI entries for ISI and HISAs at least every 6 months.	7.3.1, 7.3.2, 7.3.3
(P) Peer Review Agenda	The Peer Review Agenda (PRA) is a component of the EPA SI. ISI and HISA work product metadata, including peer review information and related documents, are entered into the SI and then published to the Agency PRA, which informs EPA website visitors about EPA's planned and ongoing peer review activities. The website for the EPA's Peer Review Agenda is http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.	7.3.3
(P) Annual Report on Peer Review to OMB	Consistent with the OMB's Peer Review Bulletin, the EPA expects to submit a report to OMB each year. This report includes information concerning the peer reviews conducted on ISI and HISAs during the previous fiscal year. The EPA generates this report from the information in the SI.	7.4

PEER REVIEW GUIDANCE

1. Peer Review at EPA: General Concepts and Context

1.1. Overview

> Peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected. Influential scientific information, including highly influential scientific assessments, should be peer reviewed in accordance with the Agency's *Peer Review Handbook*. All Agency managers are accountable for ensuring that Agency policy and guidance are appropriately applied in determining if their work products are influential or highly influential, and for deciding the nature, scope, and timing of their peer review. For highly influential scientific assessments, external peer review is the expected procedure. For influential scientific information intended to support important decisions, or for work products that have special importance in their own right, external peer review is the approach of choice. Peer review is not restricted to the nearly final version of work products; in fact, peer review at the planning stage can often be extremely beneficial.
>
> —EPA Peer Review Policy Statement, 2006

To implement the EPA's Peer Review Policy (Appendix A) effectively, individuals involved in peer review activities need to understand what peer review is and why the Agency conducts peer reviews. Those individuals also need to understand how peer review differs from activities such as peer input, stakeholder input and public comment. Familiarity with federal and EPA guidelines related to peer review is essential. This chapter discusses each of these topics and also addresses the role of peer review in regulatory development.

1.2. Peer Review

1.2.1. What Is Peer Review?

The goal of peer review is to obtain an independent review of the product from experts who have not contributed to its development.

Peer review is a documented process for enhancing a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis. (For a discussion of what constitutes a scientific or technical work product, see Section 3.1.1.) It is conducted by qualified individuals (or organizations) who are independent of those who performed the work and who are collectively equivalent in technical expertise to those who performed the original work (i.e., peers). Peer review is conducted to ensure that activities are technically defensible, competently performed, properly documented and consistent with established quality criteria. Peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria and conclusions pertaining to the scientific or technical work product, and of the documentation that supports them. Peer review also may provide an evaluation of a topic where quantitative methods of analysis or measures of success are unavailable or undefined. Peer review usually is characterized by a one-time or limited number of interactions by independent peer reviewers who provide responses to a series of questions included in a "charge" developed by EPA (see Section 6.2.1). Peer review is

encouraged during the development of a project or method, and/or as part of the culmination of the work product, as appropriate. Regardless of the timing of peer review, the goal is to ensure that the final product is scientifically and technically sound.

1.2.2. Why Use Peer Review?

Peer review is intended to identify any technical problems or unresolved issues in a preliminary (or draft) work product through the use of independent experts. This information then is used to revise the draft product so that the final work product will reflect sound scientific and technical information and analyses. To be most effective, peer review of a scientific or technical work product should be incorporated into the up-front planning of any action based on the work product; this includes obtaining the proper resource commitments (personnel and money) and establishing realistic schedules.

Although conducting a peer review requires an up-front commitment of time and resources, the benefits usually justify these added resources. Peer review enhances the credibility and acceptance of the decision based on the work product. Also, by ensuring a sound basis for decisions, cost savings are likely to be realized because decisions are less likely to be challenged.

Peer review is not free; however, not doing peer review can be costly.

1.2.3. When and How Often Should Peer Review Occur?

The Agency has significant discretion in deciding on the timing and the frequency of peer review. Options abound, each with merits depending on the context and specified peer review objectives. In many situations, a single peer review event, beginning when the final draft work product becomes available, is the approach taken. It is increasingly apparent, however, that peer review performed earlier in the work product development stages can provide a superior approach for some work products. There may be substantial incremental benefit to conducting more than one peer review during work product development, particularly when development involves complex tasks, has decision branching points, or could be expected to produce controversial findings. Sometimes additional peer reviews are conducted if the product changes significantly after the initial peer review, or if the Agency would like to know whether the peer reviewers' comments were adequately addressed in the revised product. In addition, early review could be beneficial at the stage of research design or data collection planning when the product involves extensive primary data collection. The Decision Maker (DM) should determine when the peer review(s) should occur, considering the type of work product under development and at what point a peer review would be most beneficial (see Sections 2.3.2 and 3.1.3).

Other types of work products that could benefit from early, up-front peer review in their development include scientific and technical planning products. Examples of such products are research proposals, plans and strategies. Although more than one peer review can be beneficial, the distinction between peer input and peer review should be kept in mind. Experts providing input during the development or planning stages of the work product generally do not become peer reviewers of that product. For more on this distinction, see Sections 1.2.11 and 5.2.7.

1.2.4. What Factors Are Considered in Setting the Timeframe for Peer Review?

The peer review schedule is a critical feature of the process. The schedule should take into account the availability of a quality draft work product; deadlines for the completion of a project, research program or rulemaking; funding availability; availability of qualified peer reviewers; the complexity and length

of the product; the possible need to seek public comment on the peer review product; statutory and/or court-ordered deadlines; and logistical aspects of the peer review (e.g., contracting procedures).

The time required to complete an external peer review will depend greatly on the peer review mechanism selected, ranging from several months for individual letter reviews to 10 to 12 months for a review by a federal advisory committee (FAC) *ad hoc* panel or more than a year for a review by a National Academy of Sciences (NAS) panel. Federal Advisory Committee Act (FACA) requirements for advanced notification of committee meetings and opportunities for public participation add to the time required to complete the review but enhance the transparency of the peer review process. Regardless of the peer review mechanism selected, the schedule must include adequate time to evaluate prospective peer reviewers for ethics issues such as potential conflicts of interest (COIs) or an appearance of a loss of impartiality (see Section 5.3).

1.2.5. What Budgetary Factors Should Be Considered in Planning a Peer Review?

Peer review is part of the normal cost of doing business.

Resources necessary to perform peer review should be requested as part of the costs of projects, rules or guidance. For purposes of budget planning, the costs of peer review would include the allocation of staff resources (full-time equivalents, or FTE), the contract or other costs associated with the use of outside peer reviewers and the administrative costs of conducting a review (e.g., copying, travel expenses). For peer reviews conducted by the Science Advisory Board (SAB) or Clean Air Scientific Advisory Committee (CASAC), the SAB Staff Office budgets for the peer review, including peer reviewer travel expenses, contract costs for meeting support and FTEs to support the advisory committee's work.

Senior management in EPA offices should ensure that budget requests include anticipated resources for peer review. (It should be noted that the term "EPA offices" in this Handbook refers to all headquarters, regional and program offices.) Peer review should be considered as a normal part of doing business. Peer review resource considerations also should be addressed in the analytic blueprint for Agency rulemaking actions.

1.2.6. Who Are the Peer Reviewers?

Peer reviewers are individuals who have technical expertise in the subject matter of the work product undergoing peer review. For this reason, they may be referred to as "subject matter experts." Peer reviewers should not be associated with generating the work product undergoing review; they should be able to offer independent scientific advice. Peer reviewers need to be willing participants in the peer review process; they should agree to read all materials, participate fully and act ethically. Peer reviewers should maintain the confidentiality of the product and information contained in the product (when necessary), perform the review within the agreed-upon timeframe and be unbiased and objective. Peer reviewers should disclose any activities or circumstances that could pose a conflict of interest or create an appearance of a loss of impartiality that could interfere with an objective review. See Chapter 5 for a thorough discussion of peer reviewer qualifications and ethical considerations.

1.2.7. What Is the Difference Between Internal and External Peer Review?

An internal peer review is a technical or scientific review by individuals from within the Agency who have the appropriate expertise and are independent from the development of the work product. Internal

peer reviewers should come from a different organizational unit than the one in which the work originates. Examples of internal peer review mechanisms may be found in Section 4.2.2.

An external peer review is a review by non-EPA experts with appropriate knowledge and skills who are independent from the development of the work product. External reviewers may come from other federal agencies, state and local government agencies, academia, industry, nongovernmental organizations or other outside organizations. Examples of external peer review mechanisms may be found in Section 4.2.3.

For work products that are intended to support important public policy or private sector decisions, external peer review is the approach of choice. Note that an internal peer review or technical review often precedes an external peer review. Refer to Section 4.2.1 for guidance on when to use internal and external peer reviews.

1.2.8. What Is the Difference Between Internal Peer Review and Internal Management Review?

An internal peer review is an assessment of the scientific and technical quality of a work product by independent Agency experts prior to the publication or release of the work product outside the Agency. An internal management review (sometimes referred to as "clearance") is a process for obtaining line management approvals prior to the work product's release or publication. While an internal peer review may be included as part of the internal management review (as in the case of a technical review conducted prior to the submission of a manuscript to a journal), the internal management review does not substitute for an internal peer review.

1.2.9. What Is a Letter Peer Review?

A letter review takes place when EPA seeks individual written peer review comments from independent experts, typically in the form of correspondence to EPA from the peer reviewer. The number of reviewers selected depends largely on the scientific and technical expertise required to address the issues presented in the peer review charge. Each reviewer evaluates the draft technical work product independently without consultation with other reviewers. No collaborative or consensus peer review report is developed. For letter reviews managed by a contractor, the contractor may compile all peer review comments into a single report but should not edit the comments in any way, transmitting comments unaltered to EPA. For more information on letter peer reviews, see Section 4.4.

1.2.10. What Is a Peer Review Panel?

A peer review panel is a group of experts who share and discuss their peer review comments with one another, regardless of whether the sharing takes place in a face-to-face meeting or via email or teleconference. The number of panel members selected for a peer review will depend on the issue being investigated, the time available and resources. Individuals should have appropriate scientific and technical expertise such that the review panel as a whole covers the broad spectrum of expertise necessary to address the issues and questions presented in the peer review charge. For some panels, members may be asked to prepare individual comments for submission to the Agency; for others, the panel members may be asked to collaborate and provide consensus advice in a single report to EPA. If panels provide collective or consensus (rather than individual) advice, they may be subject to the requirements of the FACA, which imposes certain open meeting, balanced membership and committee chartering requirements. For more information on peer review panels, including FACs, see Chapter 4.

1.2.11. What Is Peer Input, and How Does It Differ From Peer Review?

Peer input is not a substitute for peer review.

Peer input, sometimes referred to as peer consultation, is a form of peer involvement that generally connotes an interaction during the development of an evolving Agency work product, providing an open exchange of data, insights and ideas. Such input may be continued and iterative, and it often involves scientific and technical experts from both inside and outside the Agency. A common example is the input received from workgroup members during the development of a product.

The key distinctions between peer input and formal peer review are the independence of the peer reviewers and their level of involvement. Generally, someone who provided peer input on a work product no longer is considered independent and should not become a peer reviewer for that same work product.

Peer input provides valuable contributions to the development of the work product. Peer input does not substitute, however, for peer review. In other words, one cannot argue that a peer review is not necessary simply because a work product has received "enough" peer input.

1.2.12. What Is Stakeholder Involvement, and How Does It Differ From Peer Review?

Stakeholder involvement is not a peer review mechanism.

Stakeholder involvement occurs when the Agency engages a select set of individuals, groups or representatives from organizations or interest groups that have a stake in the outcome of the EPA's work and policies or that seek to influence the Agency's future direction to work directly on specific issues.

The Agency often seeks stakeholder involvement to ensure that all relevant facts and viewpoints related to the issue are considered. This is an interactive process that usually involves other agencies, industry groups, regulated-community experts, environmental groups and other interest groups that represent a broad spectrum of the regulated community, among others. The process of stakeholder involvement usually strives for general agreement among the involved groups and may be subject to the FACA. Stakeholders should not be involved in the peer review process if there has been prior engagement with the Agency on the development of the product or the issue. If stakeholders are involved in the peer review process, they must meet all applicable ethics laws and regulations.

Although stakeholder involvement is an outreach activity that contributes greatly to the development of a work product, it is not considered a peer review mechanism.

1.2.13. How Does Public Comment Differ From Peer Review?

The critical distinction between public comment and peer review is that public comment does not necessarily draw the kind of independent, expert information and in-depth analyses expected from the peer review process. Public comment frequently is open to all issues, and may be solicited for policy purposes or as part of the regulatory process, whereas the peer review process focuses on scientific and technical issues specified in the peer review charge.

Public comment solicited from the general public through the *Federal Register* or by other means may be required by the Administrative Procedure Act or other statutes. Public commenters usually include a

broad array of individuals; some may be scientific experts (and may provide peer input), some may be experts in other areas, and some are interested non-experts.

In terms of peer review, public comments can provide important input to the identification and selection of peer reviewers, the refinement of charge questions to be addressed in peer review, and identification of technical issues to be considered by the peer reviewers. Generally, public comment enhances the transparency of the peer review process. Although it may be an important component of the EPA's decision-making process, public comment does not substitute for peer review. See Section 7.2 for more information on public participation in the peer review process.

1.3. Policies and Guidance That Relate to Peer Review

To provide the framework for ensuring the credibility and utility of the Agency's science, EPA relies on its Peer Review Policy and peer review procedures and guidelines in this *Peer Review Handbook*; guidance from the Office of Management and Budget (OMB) Peer Review Bulletin; and the EPA's Quality System, *Information Quality Guidelines* and Scientific Integrity Policy. Each is briefly discussed below.

1.3.1. What Is the EPA's Peer Review Policy?

The EPA's Peer Review Policy[3] was first issued in 1993 and was updated in 2006 (see Appendix A). It emphasizes the critical role of peer review in ensuring that the EPA's decisions rest on sound science and data.

1.3.2. What Are the Legal Ramifications of the Peer Review Policy?

The Peer Review Policy does not establish or affect legal rights or obligations. Rather, it confirms the importance of peer review where appropriate, outlines relevant principles and identifies factors that Agency staff should consider in implementing the policy. Except where provided otherwise by law, peer review is not a formal part of, or substitute for notice-and-comment rulemaking or adjudicative procedures. The EPA's decision to conduct peer review in any particular case is wholly within the Agency's discretion. Similarly, nothing in the Peer Review Policy creates a legal requirement that EPA respond to peer review comments. To the extent that EPA decisions rely on scientific and technical work products that have been subjected to peer review, however, the remarks of peer reviewers should be included in the record for those decisions.

EPA staff and management should consult with attorney(s) in the Office of General Counsel (OGC) and/or Office of Regional Counsel (ORC), to obtain legal advice related to peer review. OGC has attorneys who are specialists in specific areas (e.g., FACA considerations, contractual responsibilities, ethics issues), and they should be consulted as needed, following consultations with local resources.

[3] EPA. 2006. *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency.* http://epa.gov/peerreview/pdfs/peer%20review%20policy%2006.pdf.

1.3.3. What Is the Office of Management and Budget's Peer Review Bulletin, and How Does It Relate to Peer Review at EPA?

OMB's *Final Information Quality Bulletin for Peer Review*[4] (see Handbook Appendix B), hereafter the OMB Peer Review Bulletin, provides guidance to federal agencies for enhancing the peer review of government science documents and establishes minimum standards for when to conduct peer review. EPA conducts peer review of its products in accordance with the guidance in the OMB Peer Review Bulletin.

OMB's Peer Review Bulletin provides two important definitions:

- **Influential Scientific Information (ISI):** Scientific information that the Agency "reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions."

- **Highly Influential Scientific Assessment (HISA):** A subset of ISI that is a scientific assessment (i.e., an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions and/or applies best professional judgment to bridge uncertainties in the available information) that "could have a potential impact of more than $500 million in any year on either the public or private sector" or "is novel, controversial, or precedent-setting, or has significant interagency interest."

Per the OMB Peer Review Bulletin, all of the Agency's ISI/HISA should be peer reviewed unless they meet specified exemption criteria (see Handbook Section 3.3). Decisions regarding categorization of products as HISA or ISI should be made early in the stages of product development; relevant guidance may be found in Section 4.2.1. The OMB Peer Review Bulletin instructs federal agencies to establish a process for public disclosure of peer review planning, including a Web-accessible description of the plan that each agency has developed for reviewing its ISI and HISAs. An agenda of the Agency's plans for reviewing these products may be found on the EPA Peer Review Agenda (http://cfpub.epa.gov/si/si_public_pr_agenda.cfm) (see Section 7.3).

1.3.4. What Is the EPA's Quality System, and How Does It Relate to Peer Review?

The Quality System framework consists of policies, procedures and oversight processes that assure the Agency's environmental data are of sufficient quantity and quality to support the data's intended use. All EPA programs generating environmental data and information, or using data and information from non-EPA sources, are to conform to the Agency's Quality Policy, CIO 2105.0 (May 5, 2000)[5], which is based on international quality standards and practices. The EPA Quality System specifies systematic planning for quality and documentation of the data quality requirements for the scientific or technical work product being developed. The Office of Environmental Information has Agency-wide oversight of the mandatory quality system, and the program and regional offices are responsible for developing a Quality Management Plan for implementing their organization-specific Quality Assurance (QA)

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[4] OMB. 2004. Memorandum for Heads of Departments and Agencies, *Final Information Quality Bulletin for Peer Review*. http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf.

[5] EPA. 2000. *Policy and Program Requirements for the Mandatory Agency-Wide Quality System*. EPA Order Classification No. CIO 2105.0. http://intranet.epa.gov/quality/documents/21050.pdf.

program. Each organization has a designated Director of Quality Assurance (DQA) or Quality Assurance Manager (QAM) responsible for quality.

QA and peer review are complementary activities and ensure that EPA uses scientifically sound data and information in making programmatic and regulatory decisions. Peer review does not replace the Agency's mandatory requirements to collect and use data of appropriate quality for the intended use in decision making. QA promotes the application of quality requirements at the project level such as determining precision, accuracy, representativeness, comparability, completeness and sensitivity of the data. Peer review primarily focuses on the scientific soundness of the results and conclusions presented in the work product. It is recognized as a valuable process that provides an objective and transparent assessment of the utility and credibility of the science. QA requirements and activities should be documented during the planning and development of the product prior to peer review. The Handbook encourages the Peer Review Leader (PRL) to contact the organization's quality assurance individual about applicable QA requirements for the product being peer reviewed. QA specifications are usually documented in a Quality Assurance Project Plan.

1.3.5. What Are the EPA's Information Quality Guidelines (IQG), and How Do They Relate to Peer Review?

The EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*,[6] better known as the EPA's Information Quality Guidelines (IQG), contain procedural guidance for ensuring that the information the Agency disseminates to the public is reliable and accurate, appropriate for its intended use, and protected from compromise (i.e., its objectivity, reliability and integrity are maintained). The EPA's IQG allows persons affected by EPA's publicly disseminated information to seek and obtain corrections from EPA (through its Office of Environmental Information). Peer review is a key step in ensuring the quality, objectivity, utility and integrity of the information that EPA disseminates.

Products undergoing peer review (pre-disseminated products) need a disclaimer.

Agency products undergoing peer review are not considered "disseminated" under the EPA's IQG because they are dynamic documents and are subject to change and, therefore, they do not represent the EPA's final decision or position. These "pre-dissemination" products should contain the following disclaimer:

> ***This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency determination or policy.***

In cases where the information is highly relevant to specific policy or regulatory deliberations, the disclaimer should appear on each page of the work product. Agency work products that are disseminated after the peer review process is completed are subject to the EPA's IQG.

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[6] EPA. 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. EPA/260R-02-008. http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

1.3.6. What Are the General Assessment Factors, and How Do They Relate to Peer Review?

The guidance titled *General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*[7] (see Appendix C) and its addendum[8] complement the EPA's IQG and Quality System and are an additional resource for EPA staff involved in the peer review process. The guidance establishes the EPA's expectations for scientific and technical information that is voluntarily submitted to or gathered by the Agency. Regardless of source, this information must be evaluated for quality and relevance prior to being used in support of EPA actions. The Agency takes into account five general assessment factors to determine whether the information meets its quality requirements: (1) soundness, (2) applicability and utility, (3) clarity and completeness, (4) uncertainty and variability, and (5) evaluation and review. The "evaluation and review" factor refers to the extent of independent verification, validation and peer review of the information. For a previous peer review to be considered adequate by the Agency, it should meet the intent of the EPA's Peer Review Policy, and the rigor of the review should be commensurate with the proposed use of the information by the Agency.

1.3.7. What Is the EPA's Scientific Integrity Policy, and How Does It Relate to Peer Review?

The EPA's *Scientific Integrity Policy*[9] facilitates scientific integrity Agency-wide through: (1) the promotion of scientific and ethical standards; (2) communications with the public; (3) the use of peer review and advisory committees; and (4) professional development. The policy promotes the culture of scientific integrity and enhances transparency within scientific processes.

The policy emphasizes the importance of ensuring that scientific studies used to support regulatory and other policy decisions undergo appropriate levels of independent peer review, and it recognizes the role of FACs (see Section 2.3.6.) in providing transparent, external peer review.

1.4. Peer Review and Regulatory Development

1.4.1. What Role Does Peer Review Have in Regulatory Development?

Peer review of scientific and technical work products that support regulations is an important, fundamental step in policy setting and regulatory development processes. A regulation itself is not subject to the Peer Review Policy. If a regulation is supported by a scientific and technical work product(s), however, that underlying work product(s) should be peer reviewed if it does not meet exemption criteria outlined in Section 3.3.

Sometimes peer review leads to recommendations for new information and analyses that would alter the work product and thus modify the scientific/technical basis for the action or rule it supports. For this reason, a completed peer review is desirable before issuing any regulatory proposal for public comment. If that is not possible logistically because of court or statutory deadlines, or other appropriate reasons,

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[7] EPA. 2003. *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*. EPA/100/B-03/001. http://www2.epa.gov/sites/production/files/2015-01/documents/assess2.pdf.

[8] EPA. 2012. *Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information. Addendum to A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*. http://www2.epa.gov/sites/production/files/2015-01/documents/assess3.pdf.

[9] EPA. 2010. *Scientific Integrity Policy*. http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf.

every effort should be made to complete the peer review before the close of the comment period. Because peer review comments on such work products could be of sufficient magnitude to warrant a revision to the proposed action or rule, every effort should be made to complete the peer review prior to the proposal stage.

1.4.2. What Is the EPA's Action Development Process (ADP), and How Does It Relate to Peer Review?

The EPA's ADP is a process designed to ensure that the Agency develops and issues high-quality rules, policy statements, guidance documents, reports to Congress and other regulatory and non-regulatory actions. It assists the Agency in achieving objectivity and transparency of information. It consists of steps for planning sound scientific and economic analyses to support the action, including peer review of any major scientific or technical work product that supports an Agency action.

1.4.3. How Does the Rulemaking Tier Affect Peer Review?

Tier 1 and Tier 2 rulemakings are, by definition, important Agency rulemakings. Therefore, work products supporting Tier 1 and Tier 2 rules should be scrutinized carefully to determine whether they should undergo peer review. In most cases, scientific and technical work products categorized as ISI or a HISA and supporting a Tier 1 or Tier 2 rulemaking should be externally peer reviewed if they do not meet exemption criteria outlined in Section 3.3.

Work products supporting Tier 3 rulemakings also may benefit from peer review. For work products supporting a Tier 3 rule, both internal and external peer review may be appropriate, depending on the nature of the product and other factors. For more information on the tiering process, see http://intranet.epa.gov/actiondp/documents/adp03-00-11.pdf. For more information on the differences between internal and external peer review, see Section 4.2.

1.4.4. Should Peer Review Be Discussed in the Analytic Blueprint for a Regulation?

Analytic blueprints are a critical part of the EPA's ADP (see Section 1.4.2). A blueprint, which is required for all Tier 1 and Tier 2 actions, spells out a workgroup's plans for the data collection and analyses that will support development of a specific action. The blueprint sets forth how this information will be collected, peer reviewed and used to craft the action within a specific budget and timeframe.

Workgroups should address peer review specifically in each analytic blueprint. For peer review purposes, development of the analytic blueprint is the process whereby the workgroup identifies supporting scientific and technical work products and recommends what kind of peer review is needed. The analytic blueprint should show the schedule of the peer review in the context of the schedule for the overall rulemaking. For more information, see http://intranet.epa.gov/actiondp/documents/adp03-00-11.pdf.

1.4.5. What Role Does Peer Review Have in Regulatory Negotiations?

As with other rules, a negotiated rulemaking itself is not subject to the Peer Review Policy. If the regulatory negotiation is supported by scientific and technical work product(s), however, that underlying work product(s) should be peer reviewed if it does not meet exemption criteria outlined in Section 3.3. This peer review should occur before the negotiation takes place, when possible.

1.4.6. Should the Peer Review Be Discussed in the Preamble of a Regulation?

For proposed and final regulations that rely on ISI and HISAs, the peer review report should be discussed in the preamble, as described in the OMB Peer Review Bulletin. The PRL should take steps to ensure that the rule writer and the regulatory workgroup are aware of this provision of the OMB Peer Review Bulletin. For peer review template language, see Appendix D, Sound Science and Peer Review in Rulemaking.

1.4.7. How Is Peer Review Documented in the Action Memorandum for Regulations?

For all rules requiring the Administrator's signature (proposed and final), the action memorandum should indicate the kind of peer review that took place. The current format for action memoranda accompanying regulatory packages is available at http://intranet.epa.gov/actiondp/adp-templates/index.htm#adp.

2. Peer Review Roles and Responsibilities

2.1. Overview

The roles defined in this chapter provide descriptions of responsibilities of key personnel involved in or conducting peer review at the Agency. These personnel are responsible for ensuring the scientific quality of work products that inform decisions.

The EPA Deputy Administrator (DA) is the senior Agency official for peer review. The DA is ultimately responsible for the performance of peer review for scientific and technical information that is intended to inform and support the EPA's environmental decisions.

The Science and Technology Policy Council (STPC), the Peer Review Advisory Group (PRAG) and the Office of the Science Advisor (OSA) oversee implementation of the Agency's Peer Review Policy. The Office of Research and Development (ORD) is responsible for maintaining the Agency's Peer Review Agenda.[10] EPA Assistant Administrators (AAs) and Regional Administrators (RAs) are responsible for making peer review decisions that are specific to their EPA offices; they may delegate some responsibilities, however, to other Decision Makers (DMs) within their organizations for planning and managing the peer review process in accordance with the Handbook guidelines. The Office of General Counsel (OGC) and Office of Regional Counsel (ORC) provide legal advice to assist Agency personnel in carrying out their peer review-related responsibilities.

Employees should be familiar with their roles and responsibilities for peer review.

Specific roles and responsibilities of agency organizations and personnel associated with peer review are discussed below. EPA employees with assigned peer review responsibilities should be familiar with the Agency's Peer Review policy and receive the appropriate peer review training. The PRAG develops and provides training on the Handbook for all employees with designated peer review responsibilities. See Section 1.2.6 for the roles and responsibilities of the peer reviewer.

2.2. Oversight Responsibilities for the EPA's Peer Review Policy

2.2.1. What Is the Role of the Deputy Administrator?

The DA has the authority to establish Agency-wide peer review policies and guidelines that enhance the credibility of EPA as a scientific agency. The DA is the final arbiter of conflicts and concerns about peer reviews conducted by the Agency.

2.2.2. What Is the Role of the Science and Technology Policy Council?

The STPC (formerly known as the Science Policy Council) is a senior Agency council chaired by the EPA Science Advisor. The STPC identifies critical science and technology policy issues and develops approaches that help advance the Administrator's environmental and public health priorities. The STPC is responsible for overseeing the implementation of the Agency's Peer Review Policy. The STPC meets its peer review responsibilities through oversight of the PRAG.

[10] EPA. 2015. *Peer Review Agenda*. http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

2.2.3. What Is the Role of the Peer Review Advisory Group?

The PRAG assists the STPC in overseeing implementation of the Agency's Peer Review Policy and serves as a technical resource for the Agency. It is a workgroup of representatives from EPA program and regional offices that was established to develop and interpret peer review guidelines, address peer review issues and promote effective peer review practices across EPA. It also serves as a cross-Agency coordination workgroup to increase the quality and consistency of peer reviews at the Agency. The PRAG is charged to perform the following duties:

- Ensure that the *Peer Review Handbook* is updated periodically.
- Develop peer review training for the agency.
- Provide expert advice to the STPC regarding peer review issues.
- Develop products for internal and external release that advance peer review in the Agency.
- Serve as a forum for discussing issues or questions relating to peer review.

2.2.4. What Is the Role of the Office of the Science Advisor?

OSA, with assistance and cooperation from all EPA program and regional offices, is responsible for producing the Agency's annual report to Office of Management and Budget (OMB) that summarizes the peer reviews that were conducted during the previous fiscal year for Influential Scientific Information (ISI), including Highly Influential Scientific Assessments (HISAs). OSA also provides support to the STPC and PRAG on peer review activities.

2.2.5. What Is the Role of the Office of Research and Development?

ORD is responsible for maintaining the EPA Science Inventory (SI) database. In addition, ORD maintains the EPA Peer Review Agenda website[11] that meets the OMB Peer Review Bulletin guidelines for a publicly available, "web-accessible listing of forthcoming influential scientific disseminations … that is regularly updated by the agency" (see Appendix B). For information on the SI and Peer Review Agenda, see Section 7.3.

2.3. Peer Review Roles and Responsibilities within EPA Offices

EPA program and regional offices are responsible for carrying out all aspects of peer review appropriate for their work products. This includes categorizing their work products as ISI, HISAs or "other," as well as determining the nature, scope and timing of the peer review and following the procedures outlined in this Handbook. For ensuring greater independence and transparency of peer reviews, it is important to separate the responsibilities for developing work products from conducting the peer review (see Figure 2), whenever possible. The roles of individuals with specific responsibilities for peer review within their organization are addressed in the following subsections.

[11] EPA. *Peer Review Agenda*. http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

2.3.1. What Is the Role of the Assistant and Regional Administrators?

The EPA's AAs and RAs are responsible for all peer review actions in their organizations. In many cases, the AA or RA may delegate these responsibilities to a DM (e.g., DAA, DRA, and Office/Division Director) within their organization. When more than one EPA office or other agencies are involved in the development of a work product, responsibility for conducting the peer review can be negotiated; often, the degree of involvement by any of the organizations and agencies and their ability to fund peer review will determine who assumes the lead for the peer review.

As part of the annual review process, AAs and RAs ensure that the peer review of influential scientific and technical work products in their program or regional office has been conducted and documented appropriately.

2.3.2. What Is the Role of the Decision Maker?

The DM should ensure that there are processes in place to determine—early in the planning stage of the product—whether the product is (or is likely to be) influential, and if influential, whether it is (or is likely to be) a HISA, and determine how the peer review is to be conducted. As noted in Section 2.3.1, the AA/RA may delegate these responsibilities to a manager within the organization, such as the ORD Laboratory or Center Director, Program Office Director, or Regional Division Director.

Specific responsibilities of the DM are the following:

- Determine which type of work products need to be peer reviewed and the nature of the peer review to be conducted for each type, and ensuring compliance with all applicable guidance (including the OMB Peer Review Bulletin).

- Identify the stages of product development for which peer review is appropriate and decide how the peer review is to be conducted.

- Document the categorization determination and other peer review planning decisions (see Roadmap Exhibit 3, Example EPA Peer Review Decision Summary Documentation), especially if the product is (or is likely to be) influential, and if influential, whether it is (or is likely to be) a HISA.

- Designate a Peer Review Coordinator (PRC) within the organization.

- Designate a Peer Review Leader (PRL) to plan, conduct and complete the peer review. The person in charge of producing the work product (Principal Investigator, Project Leader, or Project Manager (PM) – see Section 2.4.4) may serve as the PRL; however, for ISI and HISAs, the DM should consider the advantage of designating a different individual to serve as the PRL to enhance the independence of the peer review process.

- Ensure that sufficient funds are designated in the EPA office's budget to conduct the peer review and allocate adequate resources throughout the peer review process (e.g., contractor support for peer review).

- For HISAs, decide whether it is feasible and appropriate to make the draft scientific assessment available to the public for comment before or at the same time it is submitted for peer review,

and whether it is feasible and appropriate to sponsor a public meeting at which oral presentations on scientific issues can be made to the peer reviewers by interested members of the public.

- Ensure that all relevant issues and comments raised by the peer reviewer(s) are adequately addressed and documented for the record and, when appropriate, incorporated into the final work product.

2.3.3. What Is the Role of the Peer Review Coordinator?

The PRC is designated by the DM to coordinate and monitor all peer review activities related to EPA scientific and technical work products in an organization. This individual has access to senior management and all staff across the organization involved with peer review, and is the main contact with the PRAG, OSA and ORD for information about peer review activities and submissions to the SI.

Although some of the following functions might be performed by other personnel, specific responsibilities of the PRC are the following:

- Work closely with the DM and PRL to plan the peer review of the work product and ensure that peer review guidelines and procedures are appropriately applied.

- Provide advice, guidance and support to the PRL and, as determined by management, serve as the PRL for certain work products.

- Establish procedures to ensure that the peer review process is adequately documented in a peer review record (see Section 6.5) and that the record is filed and maintained in a manner consistent with Agency retention policies.

- For ISI and HISAs, ensure that information in the peer review record is consistent with OMB reporting guidelines by making key pieces publicly available on the Agency's Peer Review Agenda[12] via the SI.

- Deliver peer review training to management and staff.

- Function as the liaison with the PRAG, OSA and ORD by participating in PRAG workgroups as needed.

- Ensure that the list of work products and their associated peer review mechanisms are accurate and updated during the annual reporting (and, when necessary, at other times).

- Post or link other relevant peer review documents to the PRA from the SI.

2.3.4. What Is the Role of the Peer Review Leader for EPA-Managed Peer Reviews?

The PRL plans, conducts and completes the peer review for specific work products within an organization. The PRL is selected by the DM. To enhance the independence of the peer review process, the DM should consider the advantage of having separate individuals produce the work product and manage the peer review (see Section 2.3.2). The PRL should follow the Agency's peer review

[12] EPA. *Peer Review Agenda.* http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

procedures and guidelines and should receive training on the Handbook and other policies and guidelines applicable to peer review. For peer reviews conducted by outside organizations such as the National Academy of Sciences (NAS), the PRL should be thoroughly familiar with the ethics policies and requirements of the organization conducting the review (see Section 5.3.1).

Specific responsibilities of the PRL include:

- **Plan the peer review:** After considering the type of work product under development, the PRL (in consultation with the DM and PRC) should do the following:
    - Determine and document the categorization of the product (ISI, HISA or other) and when and how the peer review should occur.
    - Establish a plan for the peer review, including the peer review approach (e.g., letter, panel, journal, EPA- or contractor-managed peer review); the scope and timing of the peer review; and the approach to responding to peer review comments.
    - Obtain management approval of the plan, and ensure proper documentation of decisions as part of the peer review record.
    - Develop the charge for the peer reviewers, soliciting input from the project team developing the work product and the public, as appropriate. When the timing of panel selection does not allow for prior finalization of the charge, develop a preliminary version of the charge that provides enough detail about anticipated peer review scope and issue areas that requisite areas of peer review panel expertise can be identified.
    - Select peer reviewers with expertise appropriate for the charge after considering and resolving any ethics issues, including potential conflicts of interest (COIs).
    - Ensure that appropriate internal review, including clearance procedures, is completed before releasing the product for external peer review.
- **Conduct the peer review:** The PRL should:
    - Provide opportunities for public comment on the review materials, when applicable (usually for ISI or a HISA).
    - Provide the peer reviewers with materials relevant to the work product, including instructions; the charge questions; and significant scientific and technical comments, if public comment was sought. Particularly for HISA, include information about key studies or models used to support key findings or conclusions of the work product.
    - Advise peer reviewers of their responsibility to prepare their response to the charge, usually in the form of a report documenting the results of the peer review.
    - Document any changes to the charge, profile of peer reviewers or ethical conflicts that may develop, and keep the PRC informed throughout the process.

- **Complete the Peer Review:** To complete the peer review, the PRL should:
    - Ensure that peer review comments are incorporated, as appropriate, into the final work product.
    - Document the resolution in a "response to comments" or a "reconciliation memorandum," clearly identifying comments that have not been addressed.
    - Obtain the DM's approval on the resolution of peer review comments.
    - For ISI and HISAs, make the peer review report (see Table 1) and any Agency response to comments publicly available on the Agency's Peer Review Agenda.[13]
    - For ISI and HISAs, inform the PRC when the peer review is completed and available for inclusion in the annual report to OMB (see note in Section 6.4).
    - Archive the peer review record in a manner consistent with the organization's records management procedures.

2.3.5. What Are the Roles of the Peer Review Leader and Contractor in the Case of Contractor-Managed Peer Reviews?

Several responsibilities of the PRL will shift to a contractor when a contractor is managing the peer review, but the PRL still ensures the peer review is conducted and completed for a specific work product following Agency procedures. For example, consistent with the contract terms, the contractor is responsible for selecting peer reviewers with due consideration of ethics issues (such as potential COIs or an appearance of a loss of impartiality [see Section 4.6]) and the balance of expertise, providing review materials and instructions to the peer reviewers and compiling the peer reviewer comments. The PRL provides materials associated with the peer review to the Contracting Officer's Representative (COR), who is the technical point of contact for the contract. In some cases, the PRL and the COR may be the same individual. The COR then provides the materials to the contractor, who distributes them to the peer reviewers. After the peer review, the contractor ensures that the reviewers have fulfilled their responsibilities under their agreement with the contractor. EPA should not alter the contractor's peer review report. The contractor may have additional responsibilities, depending on the complexity of the peer review and public participation in the process. For more information on contractor-managed peer reviews, see Section 4.6.

2.3.6. What Is the Role of the Designated Federal Officer (DFO) in the Case of Federal Advisory Committee (FAC)-Conducted Peer Reviews?

When peer reviews are conducted through a FAC, some of the PRL responsibilities are assumed by the DFO. The DFO is an EPA employee who is responsible for managing the FAC and ensuring that the provisions of the Federal Advisory Committee Act (FACA) are met (see Section 4.7). Details of the duties and responsibilities of DFOs are available in the Agency's *Federal Advisory Committee Handbook*.[14] For example, when external peer review is conducted under the auspices of the Science Advisory Board (SAB) or the Clean Air Scientific Advisory Committee (CASAC), the SAB Staff Office

[13] EPA. 2015. *Peer Review Agenda*. http://cfpub.epa.gov/si/si_public_pr_agenda.cfm.

[14] EPA. 2013. *Federal Advisory Committee Handbook*. BiblioGov.

in the Office of the Administrator is responsible for selecting and vetting independent experts; planning, budgeting for and conducting peer review meetings; and maintaining peer review committee records.

The SAB Staff Office selects peer reviewers after a public nomination and comment process and after evaluating candidates for potential COIs or appearance of a loss of impartiality. The SAB Staff Office also announces committee meetings in the *Federal Register* and on the committee website, prepares detailed meeting minutes, transmits EPA charge and review materials to the committee and provides support to the committee in preparation of the advisory report to the EPA Administrator. To maintain the independence of the peer review process, the SAB Staff Office does not draft the EPA charge or prepare the Agency response to the peer review. The SAB Staff Office also does not enter data into the SI.

2.3.7. What Are the Roles and Responsibilities of EPA When Peer Reviews Are Conducted by the National Academy of Sciences?

The NAS is a private, nonprofit society of distinguished scientists established by Congress to provide independent, objective advice to the nation on science and technology matters. When agencies request an NAS peer review or sponsor an NAS study, a contract mechanism is used. The Agency works with NAS staff to develop a set of charge questions called a "statement of task" and also helps to define the timing and cost of the review. NAS reviews usually are conducted through the National Research Council (NRC). Once the statement of task and budget are approved by the NRC Governing Board, responsibilities for the peer review and products lie with the NAS and not EPA. The EPA contact with the NAS is a COR, and there can be more than one COR associated with an EPA-sponsored NAS review.

2.3.8. What Are the Roles and Responsibilities of EPA Authors and Managers Associated With Journal Peer Review?

The EPA considers peer review by a refereed scientific journal to be a satisfactory form of peer review to determine the scientific credibility and validity of the scientific and technical information presented in the article. Because journal peer review is an example of external review, the DM and PRL (typically one of the authors) have responsibilities for this type of peer review. The EPA authors of the article are responsible for complying with relevant organizational procedures associated with publications, such as internal review and clearance prior to submission to a journal; complying with pre-dissemination requirements, such as the use of an appropriate disclaimer; addressing peer review comments and responding to the editor; and maintaining a record of the peer review process. Peer-reviewed journal articles should be submitted to the SI as appropriate.

2.4. Other Agency Personnel Involved With Peer Review

2.4.1. What Are the Roles of the Offices of General and Regional Counsel?

OGC and ORC attorneys have specific areas of expertise, such as contracts and procurement, ethics and the FACA. They are consulted as needed to assist EPA staff with their oversight responsibilities. OGC/ORC attorney review and involvement helps ensure that Agency peer reviews meet legal standards, including those for integrity, transparency and openness.

2.4.2. What Are the Roles of the Quality Assurance Manager (QAM), Director of Quality Assurance (DQA) and Quality Assurance (QA) Staff?

The QAM, DQA and QA staff oversee implementation of the organization's Quality System pursuant to the EPA's Quality Policy for environmental data collection and use (see Section 1.3.4). QA processes and procedures are essential for developing scientifically sound, transparent and credible information supporting EPA's products and decisions. Typically, the QA staff conducts technical review of data quality and review of scientific and technical products for consistency, correctness, coherence, clarity and conformance. In planning the peer review, the PRL is encouraged to consult with the organization QA contact to determine documentation of QA requirements. If applicable, the PRL should ask the QAM to review the QA statement or QA section included in the draft or final work product.

2.4.3. What Is the Role of the Information Quality Guidelines (IQG) Officer?

The IQG Officer (or Coordinator) assists the organization in establishing pre-dissemination review procedures for the quality, objectivity, utility and integrity of the EPA's information products disseminated to the public. The PRL, PRC, QAM and DQA can collaborate with the IQG Officer to ensure compliance with the organization's established pre-dissemination procedures for the specific work products disseminated by EPA.

2.4.4. What Is the Role of the Principal Investigator (PI), Project Leader (PL) or Project Manager (PM)?

The PI, PL or PM is responsible for producing work products based on sound scientific principles and practices, and is responsible for working with the PRL to get their work products peer reviewed. The Agency's peer review procedures and guidelines, Quality Policy requirements for use of defensible data, the General Assessment Factors guidance and the Scientific Integrity Policy provide the framework for assuring the integrity and utility of the EPA's science. The PIs, PLs and PMs are expected to be familiar with these policies. The PI, PL and PM should work collaboratively with the PRC and PRL throughout the peer review process and should help develop charge questions specific to the work product. To enhance the independence of the peer review process for ISI/HISAs, a separate PRL, rather than the PI, PL or PM, should be considered to manage the peer review.

2.4.5. What Is the Role of the Contracting Officer's Representative (COR)?

For some peer reviews, a contractor takes on some of the roles of the PRL. The Contracting Officer (CO) can delegate some responsibilities to the COR. The COR is sometimes called the Project Officer, Task Order Project Officer or Work Assignment Manager. The COR provides oversight of the peer review process. In some instances, the PI, PL or PM can serve as the COR. When a contractor-managed peer review approach is used, the PRL works with and through the COR for some activities. The COR, together with the CO, is responsible for ensuring compliance with contracting requirements, developing a Statement of Work (SOW), coordinating with the contractor regarding COI and other administrative matters and overseeing contractor activities to ensure that the schedule and other contract requirements are met. Unless they also are the COR, the PI, PL or PM cannot supply materials directly to the contractor. Responsibilities of the CO also are described in Section 4.6, especially as they relate to the inclusion of COI solicitation provisions and contract clauses. In accordance with the EPA's peer review process for contractor-managed panels of ISI and HISAs, when consultation about COI is needed between the EPA Science Advisor and contractors, the CO and COR should participate in the consultation.

In some cases, the Agency may opt to obtain peer review services directly from individual peer reviewers, rather than through a contractor-managed peer review process. In such cases, the Agency generally would use a Purchase Order to compensate external peer reviewers, and the Agency contact would be the Purchasing Agent or the COR, if one is designated.

3. Categorize the Work Product and Determining the Need for Peer Review

3.1. Overview

The EPA produces or uses a variety of scientific and technical work products. Before a peer review approach can be selected, a determination first must be made and documented about whether the scientific or technical work product is influential scientific information (ISI) as defined by the Office of Management and Budget's (OMB) Peer Review Bulletin.[15] Although other scientific work products may benefit from peer review, peer review should be conducted for those that are categorized as influential. Influential scientific and technical work products generally receive internal peer review, followed by external peer review. Other work products that do not meet the OMB definition of influential products may undergo internal peer review, external peer review or both.

This chapter of the Handbook describes products that might be subject to peer review, how EPA determines whether a scientific and technical work product is influential—including whether it is a Highly Influential Scientific Assessment (HISA), which is a subset of ISI—and the critical role of senior managers in that decision (Figure 4). The distinction between ISI and HISAs is important because there are additional peer review considerations for HISAs.

3.1.1. What Are Scientific and Technical Work Products?

The first step in determining which work products should be peer reviewed is to identify those that are scientific or technical in nature. The term "scientific and technical work products" is generally consistent with the term "scientific information" in the OMB Peer Review Bulletin. Scientific and technical work products are used to support a research agenda,

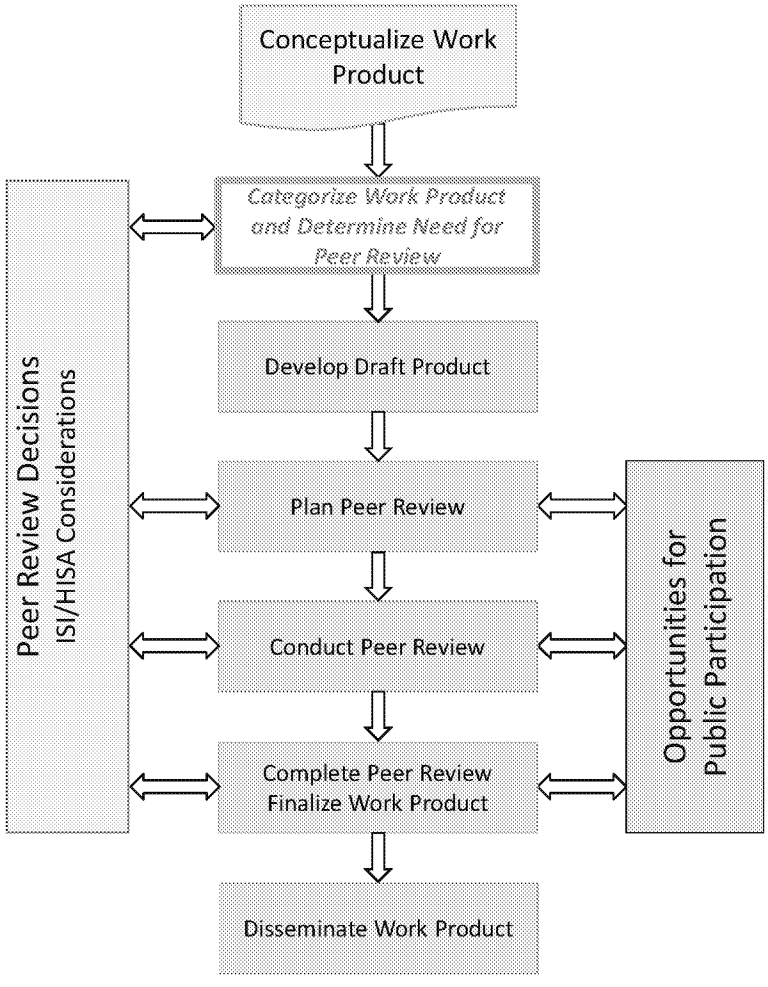

Figure 4. The Peer Review Process: Develop and Categorize Work Product/ Plan Peer Review

[15] OMB defines "scientific information" as "factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences." (OMB Peer Review Bulletin, Section I.5).

regulatory program, policy position, or other EPA position or action. Scientific and technical work products include economic and social science work products. Categories of work products include, for example, risk assessments, technical studies and guidance, analytical methods, scientific database designs, technical models, technical protocols, statistical surveys/studies, technical background materials, technical guidance (except for guidance providing policy decisions), research plans and research strategies.

Products that would not be considered scientific or technical work products can include the following:

- Products that address procedural matters (e.g., planning, reporting, coordination, notification).
- Primarily policy statements (e.g., relocation policy).
- Conference proceedings (unless the proceedings are used as the scientific basis for an Agency action or decision).
- Decision documents, such as an Environmental Impact Statement (EIS), Record of Decision (ROD), or an Economic Analysis reviewed through an interagency review process under E.O. 12866.
- Products that summarize a scientific and technical work product, including public affairs and communication materials (e.g., press releases, press kits, brochures, fact sheets); scientific abstracts, including posters and presentations at scientific meetings; or other summaries (e.g., summaries on Web pages).
- Strategic plans, Agency annual plans and budget documents, performance reports, analytical blueprints, and goals documents.

For any of these examples, the document itself is not subject to the Peer Review Policy, but the underlying scientific or technical models, data and/or work products upon which these documents are based are candidates for peer review. Scientific and technical work products that are referenced to provide context, history, or general background information and that do not materially influence or educe an agency policy or action generally need not undergo peer review.

3.1.2. Who Develops Scientific and Technical Work Products?

Scientific and technical work products may be generated by one or more EPA offices or in collaboration with external partners.[16] Scientific and technical products also may be generated by third-party organizations and used by EPA. In general, third-party scientific and technical products should be evaluated for peer review if they will be used to support Agency decisions or actions.

[16] Please note that generation of scientific or technical work products in collaboration with external partners may be subject to the Federal Advisory Committee Act (FACA).

3.1.3. What Scientific and Technical Work Products Need Peer Review?

When in doubt about whether a work product merits peer review, decide to peer review it.

According to the EPA's Peer Review Policy, "[p]eer review of all scientific and technical information that is intended to inform or support agency decisions is encouraged and expected." The OMB Peer Review Bulletin stipulates that all of the agency's ISI and HISAs should be peer reviewed unless they meet exemption criteria (see Section 3.3). Other scientific work products that do not rise to the level of influential also may be peer reviewed. These work products will have greater standing in the scientific community if an independent peer review is completed.

New applications or modifications of existing, adequately peer-reviewed methodologies or models that significantly depart from the situations for which they were originally designed may require additional peer review.

3.2. Assignment of Categories

3.2.1. What Is Influential Scientific Information (ISI)?

As defined by the OMB Peer Review Bulletin, the term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private-sector decisions. The interpretation of the term "influential" is consistent with OMB's government-wide information quality guidelines (IQG)[17] and the IQG of the Agency. (The Agency has linked its use of the term "influential" to the term "major" in its IQG).

At EPA, scientific and technical work products that will have or do have a clear and substantial impact on important public policies or private-sector decisions would be considered influential. Decision Makers (DMs) should consider the following factors when determining whether a product is likely to be influential:

- Establishes a significant precedent, model or methodology.
- Is likely to have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or state, tribal or local governments or communities.
- Addresses significant controversial issues.
- Focuses on significant emerging issues.
- Has significant cross-agency and/or interagency implications.
- Involves a significant investment of agency resources.

[17] OMB. 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication. Federal Register* 6: 8,452. February 22.

- Considers an innovative approach for a previously defined problem, process, or methodology.
- Satisfies a statutory or other legal mandate for peer review.

3.2.2. How Are ISI Determinations Made and Documented?

The DM, in consultation with the Peer Review Leader (PRL), should make the judgment as to whether a work product is ISI and document the decision. Generally, determination of whether a scientific and technical work product is influential will occur on a case-by-case basis. The EPA's work products should be evaluated and assessed with respect to the factors defined in Section 3.2.1. The categorization determination and other peer review planning decisions should be documented (see Roadmap Exhibit 3: *Example EPA Peer Review Decision Summary Documentation*).

3.2.3. What Is a Highly Influential Scientific Assessment (HISA)?

HISAs are a subset of ISI for which the OMB Peer Review Bulletin specifies additional peer review considerations, including that peer reviewers be external, non-EPA experts. OMB has defined a HISA as ISI that "the agency or the Administrator determines to be a scientific assessment that:

(i) could have a potential impact of more than $500 million in any year, or

(ii) is novel, controversial, or precedent-setting or has significant interagency interest."

OMB defines a scientific assessment as "an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information."[18] Examples given by OMB of assessments that may be considered HISAs include: state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety or ecological risk assessments;[19] toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

The more far-reaching or significant the impacts of a scientific assessment, the more appropriate it is to categorize the product as a HISA. If a work product is a scientific assessment that involves significant issues that truly are "cutting-edge," it might be appropriate to designate it as a HISA. For examples of HISA products, see the Science Inventory or the Peer Review Agenda (http://cfpub.epa.gov/si/si_public_pr_agenda.cfm).

3.2.4. How Are HISA Determinations Made and Documented?

Once a scientific or technical assessment has been determined to be influential, the DM should determine whether the product meets OMB's definition of a HISA. As with the categorization of a work product as influential, the decision whether or not to elevate a scientific assessment to the highly influential category occurs on a case-by-case basis after considering the criteria discussed in Section 3.2.3. The DM should make the judgment as to whether an assessment is a HISA and the

[18] OMB Peer Review Bulletin, Section I.7.

[19] Influential scientific information regarding human health, safety or environmental risk assessments may be subject to quality principles articulated in Section 6.4 of the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (2002, EPA/260R-02-008).

decision should be documented (see Roadmap Exhibit 3, Example EPA Peer Review Decision Summary Documentation).

3.2.5. What Work Products Are Categorized as "Other"?

Any scientific and technical work product that does not meet the OMB guidelines' criteria for influential information is categorized as an "other" work product. Examples may include, but are not limited to, journal articles and some reports. The OMB Peer Review Bulletin does not apply to journal articles because such publications do not contain findings or conclusions that represent the official position of the Agency.

3.2.6. Are Work Products Categorized as "Other" Candidates for Peer Review?

Yes, the Agency may decide to use peer review for work products categorized as "other" because of a particular EPA office's needs and goals. Peer review also may be warranted because it adds substantial value to the work product or if the work product will be used in an Agency decision-making process. Research papers submitted to peer-reviewed scientific journals are categorized as "other" yet still undergo peer review by the journal.

3.2.7. Can the Categorization of a Work Product Be Revised After the Peer Review Planning Phase?

Yes, the categorization can be revised after the peer review planning phase but before the product undergoes peer review. The nature of the work product—or its intended use—may change, so re-evaluation may be necessary to ensure an appropriate peer review is conducted.

Furthermore, the impact and interest in a peer-reviewed scientific product may change or may not be anticipated fully by the PRL or the DM. Under such circumstances, additional peer review may be necessary, including a change in the review mechanism. Any decision to modify the categorization of a work product should be documented in the peer review record (see Section 6.5.2).

3.3. Influential Work Products That Are Not Peer Reviewed

3.3.1. Under What Circumstances Are Influential Work Products Exempt From the Provisions of the OMB Peer Review Bulletin?

Per the OMB Peer Review Bulletin, the following information does not need to be peer reviewed, even if it might be considered ISI or a HISA:

- Information related to certain national security, foreign affairs or negotiations involving international trade or treaties for which peer review would interfere with the need for secrecy or promptness.

- Information disseminated in the course of an individual adjudication or permit proceeding (including a registration, approval, licensing or site-specific determination), unless the Agency determines that peer review is practical and appropriate and the influential information is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings.

- Information involving a health or safety issue where the Agency determines that the dissemination is time-sensitive.

- A regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866, *Regulatory Planning and Review*,[20] except for underlying data and analytical models used.

- Routine statistical information (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends.

- Accounting, budget, actuarial and financial information.

- Information disseminated in connection with routine rules that materially alter entitlements, grants, user fees or loan programs, or the rights and obligations of recipients thereof.

3.3.2. Are There Other Circumstances When Peer Review of Influential Products Is Not Necessary?

Yes, there are other circumstances when peer review of influential products may not be necessary. For example, peer review generally is not conducted:

- For work that has been reviewed previously in a manner consistent with the OMB Peer Review Bulletin and this Handbook (e.g., a cancer risk assessment methodology or an exposure modeling technique that was the subject of earlier peer review of appropriate technical merit would not generally undergo additional peer review even if the product supported a significant Agency decision).

- If an application of an adequately peer-reviewed work product does not depart significantly from its scientific or technical approach.

- When the scientific or technical methodologies or information being used are commonly accepted in the field of expertise and have the appropriate documentation to support the commonly held view (e.g., many products supporting Control Techniques Guidelines and Effluent Limitation Guidelines).

- When the product was developed by the National Academy of Sciences (NAS).

3.3.3. For Influential Information That Is Not Exempt, Can the Peer Review Provisions of the OMB Peer Review Bulletin Be Waived or Deferred?

The Administrator may waive or defer the peer review provisions of the OMB Peer Review Bulletin for ISI (including HISAs) if there is a compelling rationale for the waiver or deferral. The use of waivers is expected to be limited to unusual and compelling situations not otherwise covered by the exemptions, such as situations in which unavoidable legal deadlines prevent full implementation of the OMB Peer Review Bulletin's peer review provisions. According to the Bulletin, deadlines found in consent decrees ordinarily will not warrant waiver of the provisions because those deadlines should be negotiated to

[20] Executive Order No. 12866. October 4, 1993. *Federal Register,* 51:735. http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf.

permit time for conducting a peer review. Deferral of some or all of the peer review provisions may be an appropriate way to accommodate immovable deadlines. If any of the OMB Peer Review Bulletin provisions are deferred, peer review should be conducted as soon as practicable thereafter. Deferrals of peer review of ISI and HISAs should be approved by the Administrator.

If peer review of an influential work product is not planned, an explanation should be included in the product documentation and record for that work product in the Science Inventory (SI).

3.4. Work Products from Contracts, Grants and Agreements That May Require Peer Review

The Agency should not use scientific and technical work products from contracts, grants or cooperative agreements to support decision making unless the work products have undergone a peer review both for scientific and technical rigor and for applicability to the specific use to be made of the product. Products generated by contractors under the direct supervision of EPA and incorporated by the Agency in the development of EPA scientific and technical work products are not necessarily peer reviewed separately but as part of the final Agency product.

Contracts differ from grants and cooperative agreements and require special considerations when considering peer review of these work products (see Section 3.4.2). There are important legal restrictions on the direct use of work products developed under grants and cooperative agreements in the agency's decision-making process. See the EPA's Grants and Debarment Web page (http://www.epa.gov/ogd/ or http://intranet.epa.gov/OGD/policy/7.0-GPI-GPI-94-04.htm) for additional information.

3.4.1. How Does the EPA's Peer Review Process Apply to Products Generated through EPA Contracts?

A work product generated through an EPA contract should undergo the same degree of peer review as if the work product was developed by an EPA employee. The peer review should be conducted independently from the contractor who developed the work product. EPA is responsible for arranging the peer review (see Section 4.6.1).

3.4.2. How Does the EPA's Peer Review Process Apply to Products Generated through EPA Assistance Agreements (e.g., Grants or Cooperative Agreements)?

Special considerations apply to the peer review of scientific and technical work products generated through EPA grants or cooperative agreements.

EPA provides financial assistance for research that is intended to stimulate or support development of scientific knowledge that is not primarily for EPA's direct use or benefit. The resulting work products might be widely disseminated either through publication in scientific journals or through other means, as opposed to a report tailored to the EPA's specific needs and requirements. EPA can consider these work products just as it does other published scientific works when formulating its programs and policies. EPA may determine that the recipient's work product is influential because (1) it will be used to support an EPA program or policy position; and (2) it meets the criteria for influential information. EPA should evaluate whether the peer review process undertaken by the assistance agreement recipient was acceptable for the purposes for which EPA plans to use the work product. EPA may accept the peer review if it determines that it is of appropriate quality and as defensible as if it were conducted by EPA

itself. The work product may require additional peer review, however, in the context of its use or modification by the Agency.

The following are options for peer reviewing the product:

- EPA can have the product peer reviewed with the participation of the assistance agreement recipient/author(s). In this case, EPA could arrange for an independent peer review of the product within the context of the way(s) in which the Agency plans to use it. EPA may ask the recipient/author(s) to provide additional information or to revise the product in response to the peer review.

- EPA can have the product peer reviewed without the participation of the recipient/author. EPA could arrange for the peer review of the product within the context of the Agency's intended use. EPA then would receive the comments and prepare a statement that documents the EPA's own response to the comments.

3.4.3. Can the Recipient of a Grant or Cooperative Agreement Use Agreement Funds to Pay Peer Reviewers of Their Work Products?

Provided that EPA agrees that a peer review would further the public purpose of the assistance agreement, EPA may include funds for the peer review in the agreement. This is generally in the form of journal publication fees. If a work product is ISI or a HISA, the peer review of that product should follow the guidelines set out in the *Peer Review Handbook*, consistent with Agency use and review of the product.

3.4.4. How Should Peer Review Be Handled for Products Developed Under an Interagency Agreement?

Under an Interagency Agreement, EPA provides funds to another agency to be used for a specific purpose. The receiving agency's guidance for peer review is likely to be different from the EPA's Peer Review Policy, although the OMB Peer Review Bulletin establishes some minimum common guidance for the federal government. Regardless, if EPA plans to use any work products from that agreement, a determination should be made as to whether the work products are ISI, including whether they are HISAs, or do not qualify as influential (i.e., "other"). The EPA then should decide whether those documents need review under the EPA's Peer Review Policy and pursue the appropriate mechanism.

3.5. Other Types of Work Products That May Require Peer Review

3.5.1. Should Another Organization's Work Products That Have Been Submitted to the EPA for Use in Decision Making Be Peer Reviewed?

Any scientific or technical work product that is used in agency decision making and is considered influential becomes a candidate for peer review, regardless of whether the work product is developed by EPA or another organization. Therefore, all work products important to EPA decision making that are independently generated by other organizations (e.g., other federal agencies, interagency groups, state and tribal bodies, environmental groups, industry, educational institutions, international bodies) should be considered as candidates for peer review. The DM in the EPA office planning to use the product is responsible for the categorization and decision regarding peer review.

If possible, when EPA knows that a work product being generated by another organization may be of interest to EPA for future use, the appropriate EPA office(s) should work with that organization and others, as appropriate (e.g., state agencies, international organizations), to promote the use of peer review. Furthermore, when another agency's product is being considered for EPA use, the EPA office(s) planning to use the product should ascertain—in collaboration with other EPA offices as appropriate—the characteristics and sufficiency of any peer review process already conducted or planned for the candidate product.

Reports produced by certain outside organizations—such as the NAS, the EPA's Science Advisory Board (SAB) and the International Agency for Research on Cancer—are products of independent peer review by their nature. The OMB Peer Review Bulletin specifically notes that official NAS reports are generally presumed not to require additional peer review. The Agency's scientific work products which use and interpret those products' findings or results may be subject to peer review. Peer reviews conducted by stakeholders of their own products may be considered peer input but not independent peer review, unless principles and policies articulated in the EPA's *Peer Review Handbook* can be applied.

3.5.2. Is Additional Peer Review Necessary If a Paper Is Published in a Refereed Scientific Journal?

The extent to which additional peer review is needed for an article that has been peer reviewed by a credible refereed scientific journal depends upon EPA's use of the article. For example, EPA may determine that an additional and more rigorous or transparent review process is needed if a particular journal review process did not address questions that EPA determines should be addressed before using or disseminating the information.

3.5.3. Does an Agency Work Product Become a Candidate for Peer Review When Peer-Reviewed Journal Articles Are Used in Support of That Work Product?

Agency work products are candidates for peer review even when supported by peer-reviewed journal article(s). Although the use of articles that have been peer reviewed by a credible journal strengthens the scientific and technical credibility of any work product in which the article(s) appears or is referenced, it does not eliminate the need to consider whether the work product itself should be peer reviewed. In most cases, journal peer review may not cover issues and concerns that the Agency may want peer reviewed to support an EPA action. Under these circumstances, the scientific or technical work product in which the article(s) appears or is referenced becomes a candidate for peer review. A journal article authored by EPA employees should be used in the same manner as an article published by non-EPA authors in a credible, well-recognized journal.

Decisions to peer review a work product should be documented in the peer review record (see Section 6.5.2).

3.5.4. Should Site-Specific Decisions Be Subject to Peer Review?

A site-specific decision (e.g., for a permit or hazardous waste cleanup) itself is not subject to peer review under the EPA's Peer Review Policy. However, if a site-specific decision is supported by ISI or a HISA generated for that site-specific decision, then that work product should be peer reviewed. Generally speaking, the PRL should examine closely the ways in which the underlying scientific or technical work product is adapted to the site-specific circumstances.

3.5.5. Should National Environmental Policy Act (NEPA) Products Be Subject to Peer Review?

Although an EIS prepared under the requirements of the NEPA receives extensive review through the "scoping" and interagency and public review processes that are part of the NEPA, this usually is not considered peer review. If the underlying scientific or technical data, models, analyses or work products are categorized as ISI or a HISA, then these should be peer reviewed.

If EPA is developing the NEPA document as part of an EPA action/decision (i.e., EPA is the lead agency under NEPA), and supporting documents are ISI or HISAs, then the supporting documents should receive independent peer review. If the document is not categorized as influential, then peer input might be appropriate.

If EPA is reviewing an EIS from another agency (i.e., EPA is not the lead agency under NEPA), it is likely that it is being reviewed for conflicts with EPA policy and general environmental concerns. In such a case, EPA should ask whether the underlying scientific or technical work product that supports the EIS has been peer reviewed to avoid concerns about the full credibility and soundness of the EIS based on the science and technical support. The EPA should work with the other organization/agency to ensure that scientific and technical work products receive peer review adequate for EPA purposes.

3.5.6. Do Voluntary Consensus Standards Undergo Peer Review?

In general, the answer is no. The National Technology Transfer and Advancement Act of 1995 (NTTAA) directs EPA to use available voluntary consensus standards in its regulatory activities, unless to do so would be inconsistent with applicable laws or otherwise impractical. For purposes of the NTTAA, voluntary consensus standards are defined as technical standards (e.g., materials specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus bodies (e.g., ASTM International). The general purpose of the NTTAA is to reduce private and governmental costs by avoiding having the government "reinvent the wheel" in the development of technical standards. Voluntary consensus standards normally would not undergo peer review because the underlying process used by issuing organizations to develop and approve these standards generally is considered adequate for purposes of the Agency's Peer Review Policy.

3.5.7. What Economic Work Products Need Peer Review?

Economic work products are considered scientific and technical work products. As such, it may be appropriate to peer review them, and an ISI/HISA/other determination should be made. If an economic work product is determined to be influential, then it should be peer reviewed if it has not been subjected already to adequate peer review according to the relevant sections of this Handbook or is otherwise exempt (see Section 3.3).

Data and analytical models underlying an economic analysis, particularly those supporting economically significant rules, are candidates for peer review if the models and corresponding use of the data have not been subjected previously to adequate peer review. This also is true for work products that will serve as a principal method or protocol used to conduct economic analyses within a program.

The following economic work products generally should be peer reviewed:

- Internal Agency guidance for conducting economic and financial analysis that meets the definition of influential.

- Economic and financial methodologies that will serve as a principal method or protocol used to conduct economic analyses within a program.

- Unique or novel applications of existing economic and financial methodologies, particularly those that are recognized to be outside of mainstream economic practices.

- Broad-scale economic analyses of regulatory programs, such as those required by Congressional mandates (e.g., the Clean Air Act reports to Congress on benefits and costs).

- Stated preference (e.g., contingent valuation) and revealed preference surveys (e.g., recreational travel cost surveys) developed to assist in the economic analysis of a regulation or program.

- National surveys of costs and expenditures for environmental protection (e.g., financial needs surveys, pollution abatement expenditures surveys).

- Economic multiyear research plans developed to assess and advance the state-of-science in economic theory, methodologies or modeling (in particular, the technical feasibility of the plan's components).

- Meta-analyses (i.e., re-analyses of existing published literature and supporting data on the measurement of economic benefits, costs and impacts) developed to assist in the economic analysis of a regulation or program.

Other economic work products also might benefit from peer review, even though they do not exhibit a high degree of complexity or establish an innovative approach. For these, factors such as the potential significance of the analysis for cross-agency or interagency practices or the significance of the issue addressed may make peer review desirable. Examples include:

- Analyses measuring the economic impacts and effectiveness of adopting market-based or economic incentives as regulatory management instruments.

- Technical analyses supporting economic policies established under other government organizations (e.g., economic models used to study transportation, economic development and international trade policies).

External peer reviews can be provided by the SAB's Environmental Economics Advisory Committee, other appropriate outside organizations, or individual, non-EPA reviewers who have expertise in the technical economic issues raised in the economic work product.

3.5.8. Should Economic Analyses Prepared in Support of "Major" or "Economically Significant" Regulations Be Peer Reviewed?

If an Economic Analysis or Regulatory Impact Analysis[21] uses accepted, previously peer-reviewed methods in a straightforward manner, it would not undergo additional peer review. The OMB Peer Review Bulletin specifically exempts Economic Analyses already reviewed through an interagency review process that involves application of the principles and methods defined in OMB Circular A-4.[22] Furthermore, Economic Analyses prepared to support "major" or "economically significant" regulations[23] typically do not utilize innovative or untried economic methods. It is unnecessary to conduct peer reviews of straightforward applications or transfers of accepted, previously peer-reviewed economic methods or analyses (including those published in peer-reviewed journals). Therefore, Economic Analyses that are developed using these procedures do not normally undergo an additional peer review, even those Economic Analyses prepared in support of "major" and "economically significant" rules.

Even when peer review is not required, additional peer input can be beneficial in the development of economic work products for "major" and "economically significant" rules, and this input is encouraged by the OMB Peer Review Bulletin. At present, some peer input of these analyses already is likely to be included as part of the regulatory development process, including input received from other EPA offices represented on the workgroup for the rule, from the Agency's Regulatory Steering Committee, and from the public as part of the public comment process for the rule. There may be, however, added benefit to employing additional peer input procedures, such as actively soliciting input from economists elsewhere in the Agency (through the Economics Forum Steering Committee or the National Center for Environmental Economics), as well as economists from other federal agencies, on the quality and completeness of the Economic Analysis. It is unnecessary to conduct peer reviews of straightforward applications or transfers of accepted, previously peer-reviewed economic methods or analyses, (including those published in peer-reviewed journals).

3.5.9. What Other Social Science Work Products Need Peer Review?

Typically, a social science work product is one that includes empirical, logic-based approaches to answer technical questions about human motivation, human behavior, social interactions and social processes that are relevant to the environmental issues being addressed. The term "behavior" includes overt actions; underlying psychological processes, such as cognition, emotion, temperament and motivation; and bio-behavioral interactions. The term "social" includes socio-cultural, socio-economic and socio-demographic status; bio-social interactions; and the various levels of social context, from small groups to complex cultural systems. Examples of social science work products include analyses

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[21] The OMB Peer Review Bulletin refers to Economic Analyses as Regulatory Impact Analyses.

[22] OMB. 2003. *Circular A-4, Regulatory Analysis.* http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf. September 17.

[23] Under Section 3(f)(1) of Executive Order 12866 (58 *Fed. Reg.* 51,735 [Oct. 4, 1993]), "significant regulatory actions" rules are those that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or state, local or tribal governments or communities. The term "major," as defined in the Congressional Review Act (5 U.S.C. § 804(2)), means a rule that has resulted in or is likely to result in: an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, federal, state or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets.

and/or evaluations related to such topics as pollution prevention, risk communication, environmental information, environmental justice, quality of life, decision making and public participation.

The following social science work products normally should undergo external peer review:

- Internal Agency guidance for conducting social impact assessments and other community cultural assessments related to different environmental protection approaches, such as community-based watershed protection (heretofore referred to as social assessments).

- New social science methodologies that will serve as a principal method or protocol to conduct social assessments.

- Unique or novel applications of existing social science methods, such as surveys, focus groups, interviews, network analyses, comparative analyses and content analyses.

- New national surveys of values, perceptions and preferences related to environmental protection.

- Innovative research or analyses that address the human dimensions of environmental protection or environmental change in terms of social trends, future predictions and/or behavioral generalizations.

- Social science multiyear research plans developed to assess and advance the state-of-science in social science theory, methodologies or modeling (in particular, the technical feasibility of the plan's components).

3.5.10. Are Regulations Subject to Peer Review?

A regulation itself is not subject to the Peer Review Policy. However, all ISI and HISAs that support a regulatory action should be peer reviewed. The administrative record for the action should include a statement certifying how the peer review provisions have been met (see Appendix D). For discussion of the role of peer review in regulatory development, see Section 1.4.

3.5.11. Should Environmental Regulatory Models Be Peer Reviewed?

In general, the answer is yes. Guidelines for the peer review of environmental regulatory models have been published by the Agency. These can be found on the EPA website under http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1003E4R.PDF.

4. Peer Review Types and Mechanisms

4.1. Overview

After a planned work product has been categorized as Influential Scientific Information (ISI); a Highly Influential Scientific Assessment (HISA), which is a subset of ISI; or "other," the selection of a peer review approach is needed and involves consideration of many aspects. This chapter outlines the steps for a range of peer review options and discusses the processes and considerations relevant to each (Figure 5). The EPA develops various scientific work products that may be used to support its analyses and decisions. These products vary widely in their complexity and levels of influence. Although much attention is given in this Handbook to influential information, selecting the appropriate type of review mechanism also is important for work products categorized as "other." This chapter, therefore, applies to all products that warrant peer review, not only work products categorized as ISI or a HISA. In addition, although the peer review principles in this Handbook apply to both internal and external peer reviews, the emphasis of this chapter is on options for obtaining external reviews.

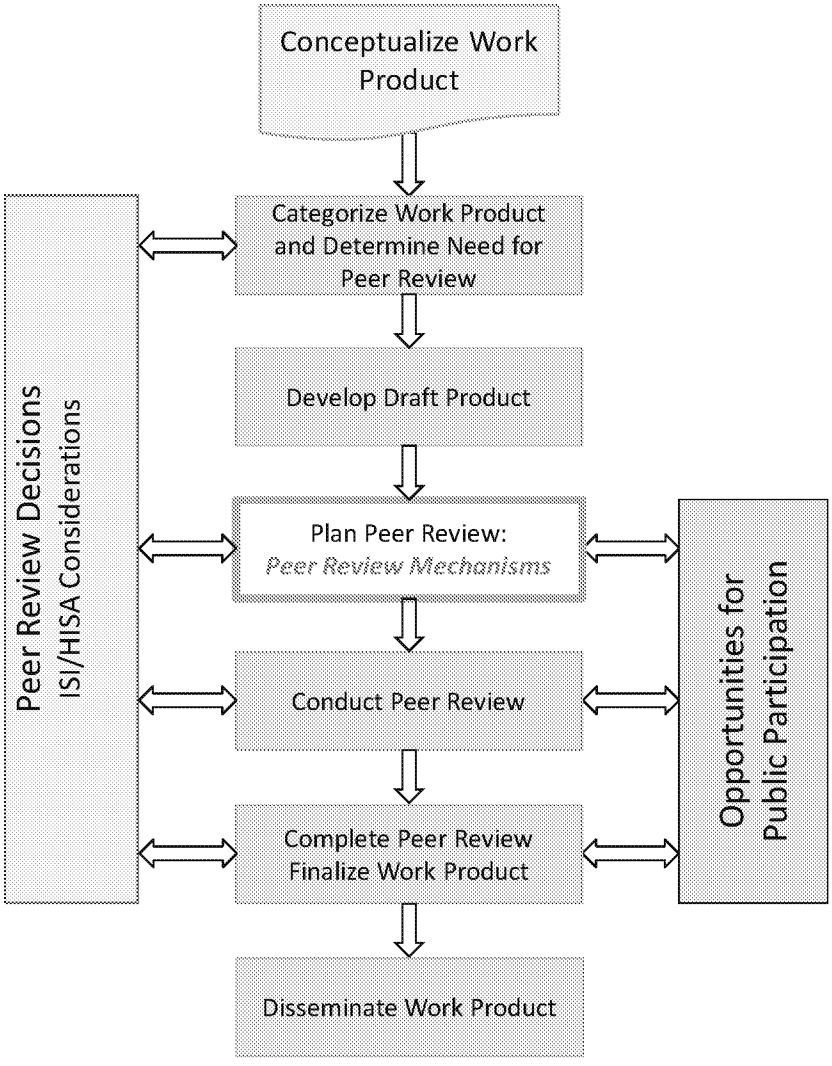

Figure 5. The Peer Review Process: Peer Review Mechanisms

4.2. Choosing a Peer Review Mechanism

The preamble to the Office of Management and Budget's (OMB) Peer Review Bulletin[24] notes that

> "… different types of peer review are appropriate for different types of information. Under this Bulletin, agencies are granted broad discretion to weigh the benefits and costs of using a particular peer review mechanism for a specific information product. The selection of an appropriate peer review mechanism for scientific information is left to the agency's discretion."

[24] OMB. Dec. 16, 2004. Memorandum for Heads of Departments and Agencies, *Final Information Quality Bulletin for Peer Review*. http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf.

4.2.1. How Is the Appropriate Peer Review Mechanism Determined?

During the planning of a peer review, the Decision Maker (DM), the Peer Review Coordinator (PRC) and the Peer Review Leader (PRL) may consider several mechanisms for the peer review of a scientific or technical work product. Options range from formal review by EPA colleagues not involved in developing the product (internal peer review or Agency review) to a large and formal panel of subject matter experts from outside EPA (external panel of independent peer reviewers) to a combination of internal and external peer reviews. The peer review effort might be a focused one-time evaluation, or it might encompass several examinations over the course of a product development. Peer review provides the greatest credibility for the EPA's scientific and technical work products when it involves qualified, external independent reviewers; is intensive in its examination; and operates through a formal and transparent process. Per the EPA's Peer Review Policy, external peer review is the approach of choice for all ISI and is the expected procedure for a HISA. Time and resource considerations, however, may impose limitations on the type of peer review performed. If only an internal peer review is planned for scientific and technical work product(s) categorized as ISI or HISAs, the rationale for doing this should be documented and approved by the DM.

Arranging for the most appropriate and feasible peer review will involve a judgment regarding the extent to which the peer review will improve the credibility of the product, as well as consideration of substance, time, resources, priorities and capacity of peer review mechanisms. The PRL should develop a peer review plan for early consideration by the DM (and PRC). For influential work products, including HISAs, public comments on the peer review plan posted on the Science Inventory (SI) (see Section 7.3.4) may lead the Agency to modify the peer review approach, for example, to employ a public panel review process rather than letter reviews.

The mechanism of the peer review should match the importance and complexity of the work product.

The approach best suited to a specific work product will depend on the nature of the topic and the intended use of the final product. Generally, the more novel or complex the science or technology, the greater the cost implications of the impending decision or public policy, and the more controversial the issue, the stronger the indication is for a more extensive and involved peer review and for an external peer review in particular. Certain work products may lend themselves clearly to extensive external peer review; generally, these will be products with large impacts. Other work products may not need a large-scale external peer review and may utilize a less involved, less resource-intensive review.

It is important to make the choice of peer review mechanism at the time that the work is planned (for products supporting rulemakings, at the analytic blueprint stage) so that peer review costs and time can be budgeted into the work plan. Essentially, the level of peer review should match the impact and complexity of the work product. For example, a Tier 1 or Tier 2 rule under development carries considerable weight and deserves careful handling and attention; therefore, in cases where the Agency has determined that a supporting work product should be peer reviewed, that peer review deserves a commensurate level of care and attention.

Factors that should be considered in selecting a peer review approach include the categorization of the work product (ISI, HISA or other), the availability of internal or external qualified reviewers with the required expertise, whether individual or group advice is desired, and the provision for opportunities for the appropriate level of public participation. Timing and budgetary considerations also may be factors. No single peer review mechanism is likely to work best in all situations; the DM, PRC and PRL should consider, however, the following general guidance:

- For ISI and HISAs intended to support the most important decisions, or for work products that have special importance in their own right, the recommended approach is an internal review followed by an external peer review. Generally, the more complex, novel and/or controversial the product, or the higher impact it is likely to have, the more the DM should consider implementing a peer review involving external experts and providing opportunities for public participation.

- HISAs (a subset of ISI) are expected to undergo rigorous external peer review with opportunities for public participation. When time and resources allow, panels are preferable. External panels usually will be managed by a contractor or conducted by a federal advisory committee (FAC).

- Work products that are less complex, novel or controversial, or that have a lower impact, may be subject to less extensive, less resource-intensive review processes.

- Group discussion among peer reviewers (i.e., panel reviews) can be very helpful in the peer review process because it allows interaction among peer reviewers with different perspectives and expertise. Peer review panels to which the public is invited are more transparent than closed discussions.

- In general, more reviewers are necessary for complex projects (to ensure that expertise from more disciplines is represented) and for controversial topics (to represent differences in scientific perspective within a discipline).

- Strict time constraints, such as a court-ordered deadline, can make a less involved or less formal peer review mechanism imperative. DMs and PRLs should make maximum efforts to ensure that such a process is systematic and objective.

- Reviews of products from remediation and other programs may be tied to litigation; the Office of General Counsel (OGC) or the Office of Regional Counsel (ORC) should be consulted regarding any restrictions to be aware of before deciding what peer review mechanism to use.

4.2.2. What Are Some Examples of Internal Peer Review Mechanisms?

The following are examples of internal peer review mechanisms:

- Individual letter review by independent EPA experts (e.g., a review by Office of Research and Development [ORD] experts of a draft article on benchmark dose completed by a program office).

- *Ad hoc* panel of independent EPA experts (e.g., an independent internal workgroup convened to review the science supporting the possible classification of a chemical as a carcinogen).

- Technical review by scientists in an EPA laboratory, typically conducted by letter (e.g., an initial review of the risk assessment for a regional incinerator by agency scientists), prior to submission to a journal.

4.2.3. What Are Some Examples of External Peer Review Mechanisms?

Examples of external peer review mechanisms include the following:

- Review of a journal manuscript by a refereed scientific journal.
- Letter review by individual independent experts from outside the Agency.
- *Ad hoc* panel of independent non-EPA experts convened for review and discussion, with each panelist submitting his/her comments separately.
- Review by an established FAC (e.g., a review of an Integrated Scientific Assessment document for a criteria air pollutant by the Clean Air Scientific Advisory Committee [CASAC]).
- Agency-appointed special board or commission (e.g., a review of the risk assessment methodology prepared by the Clean Air Act Commission on Risk Assessment). OGC should be consulted to determine whether the Agency has specific statutory authority to establish and finance the activities of a board or commission that would perform governmental functions and whether the Federal Advisory Committee Act (FACA) would apply to the board or commission.
- Review by the National Academy of Sciences (NAS) under a contract with EPA.

There are other bodies that may provide external commentary on Agency work products but are not considered peer review mechanisms, such as the following:

- Interagency committees (e.g., a review of prospective research plans by the Committee on the Environment, Natural Resources, and Sustainability, coordinated by the White House).
- Committees convened by another federal agency or government organization (e.g., a review of the Dioxin Reassessment by the Health and Human Services Committee to Coordinate Environmentally Related Programs).
- Reviews initiated by nongovernmental groups (e.g., a Society for Risk Analysis review of cancer guidelines).

4.3. Mechanism: Journal Peer Review

Peer review of journal articles performed by a credible, refereed scientific journal contributes to the scientific and technical credibility of the reviewed product. Generally, EPA considers peer review by such journals as adequate for reviewing the scientific credibility and validity of the findings (or data) in that article and, therefore, a satisfactory form of peer review.

Prior to submitting an article to a journal for peer review, EPA employees are encouraged to have the article internally peer reviewed. Articles also may need examination in accordance with any organizational clearance procedures, especially when the author includes EPA as their affiliation. For EPA employees, Conflict of Interest (COI) law and policy also will apply.

The OMB Peer Review Bulletin does not apply to journal articles because such publications do not contain findings or conclusions that represent the official position of the Agency (i.e., they are categorized by the Agency as "other"). Therefore journal articles must have the appropriate disclaimer